# Index

<table>
<thead>
<tr>
<th>Index</th>
<th>499.05</th>
<th>Chapter 499, Part III</th>
<th>61N-1.016</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>61</td>
<td>76</td>
<td>119</td>
</tr>
<tr>
<td>Chapter 499, Part I</td>
<td>499.051</td>
<td>499.81</td>
<td>61N-1.017</td>
</tr>
<tr>
<td>3</td>
<td>61</td>
<td>77</td>
<td>121</td>
</tr>
<tr>
<td>499.001</td>
<td>499.052</td>
<td>499.82</td>
<td>61N-1.018</td>
</tr>
<tr>
<td>4</td>
<td>62</td>
<td>77</td>
<td>121</td>
</tr>
<tr>
<td>499.002</td>
<td>499.055</td>
<td>499.83</td>
<td>61N-1.019</td>
</tr>
<tr>
<td>4</td>
<td>62</td>
<td>79</td>
<td>123</td>
</tr>
<tr>
<td>499.003</td>
<td>499.057</td>
<td>499.831</td>
<td>61N-1.020</td>
</tr>
<tr>
<td>5</td>
<td>63</td>
<td>80</td>
<td>124</td>
</tr>
<tr>
<td>499.005</td>
<td>499.06</td>
<td>499.832</td>
<td>61N-1.021</td>
</tr>
<tr>
<td>11</td>
<td>63</td>
<td>81</td>
<td>124</td>
</tr>
<tr>
<td>499.0051</td>
<td>499.062</td>
<td>499.833</td>
<td>61N-1.022</td>
</tr>
<tr>
<td>13</td>
<td>64</td>
<td>81</td>
<td>124</td>
</tr>
<tr>
<td>499.0054</td>
<td>499.065</td>
<td>499.834</td>
<td>61N-1.023</td>
</tr>
<tr>
<td>17</td>
<td>64</td>
<td>82</td>
<td>125</td>
</tr>
<tr>
<td>499.006</td>
<td>499.066</td>
<td>499.84</td>
<td>61N-1.024</td>
</tr>
<tr>
<td>18</td>
<td>65</td>
<td>83</td>
<td>128</td>
</tr>
<tr>
<td>499.007</td>
<td>499.0661</td>
<td>499.85</td>
<td>61N-1.0245</td>
</tr>
<tr>
<td>19</td>
<td>66</td>
<td>83</td>
<td>131</td>
</tr>
<tr>
<td>499.008</td>
<td>499.067</td>
<td>499.86</td>
<td>61N-1.025</td>
</tr>
<tr>
<td>21</td>
<td>68</td>
<td>84</td>
<td>132</td>
</tr>
<tr>
<td>499.009</td>
<td>Chapter 499, Part II</td>
<td>69</td>
<td>499.87</td>
</tr>
<tr>
<td>21</td>
<td>69</td>
<td>84</td>
<td>133</td>
</tr>
<tr>
<td>499.01</td>
<td>499.601</td>
<td>499.88</td>
<td>61N-1.027</td>
</tr>
<tr>
<td>22</td>
<td>69</td>
<td>85</td>
<td>135</td>
</tr>
<tr>
<td>499.012</td>
<td>499.61</td>
<td>499.89</td>
<td>61N-1.028</td>
</tr>
<tr>
<td>30</td>
<td>70</td>
<td>85</td>
<td>136</td>
</tr>
<tr>
<td>499.01201</td>
<td>499.62</td>
<td>499.90</td>
<td>61N-1.029</td>
</tr>
<tr>
<td>39</td>
<td>70</td>
<td>86</td>
<td>142</td>
</tr>
<tr>
<td>499.0121</td>
<td>499.63</td>
<td>499.91</td>
<td>61N-1.030</td>
</tr>
<tr>
<td>40</td>
<td>71</td>
<td>86</td>
<td>142</td>
</tr>
<tr>
<td>499.01211</td>
<td>499.64</td>
<td>499.92</td>
<td>61N-1.031</td>
</tr>
<tr>
<td>46</td>
<td>71</td>
<td>87</td>
<td>144</td>
</tr>
<tr>
<td>499.015</td>
<td>499.65</td>
<td>499.93</td>
<td>61N-1.032</td>
</tr>
<tr>
<td>46</td>
<td>72</td>
<td>88</td>
<td>145</td>
</tr>
<tr>
<td>499.023</td>
<td>499.66</td>
<td>499.931</td>
<td>Part 205</td>
</tr>
<tr>
<td>48</td>
<td>72</td>
<td>88</td>
<td>147</td>
</tr>
<tr>
<td>499.024</td>
<td>499.67</td>
<td>499.94</td>
<td>§205.2</td>
</tr>
<tr>
<td>48</td>
<td>73</td>
<td>88</td>
<td>147</td>
</tr>
<tr>
<td>499.025</td>
<td>499.68</td>
<td>Chapter 61N-1</td>
<td>§205.3</td>
</tr>
<tr>
<td>48</td>
<td>73</td>
<td>89</td>
<td>147</td>
</tr>
<tr>
<td>499.028</td>
<td>499.69</td>
<td>61N-1.001</td>
<td>§205.4</td>
</tr>
<tr>
<td>49</td>
<td>73</td>
<td>89</td>
<td>148</td>
</tr>
<tr>
<td>499.029</td>
<td>499.701</td>
<td>61N-1.006</td>
<td>§205.50</td>
</tr>
<tr>
<td>51</td>
<td>74</td>
<td>93</td>
<td>148</td>
</tr>
<tr>
<td>499.0295</td>
<td>499.71</td>
<td>61N-1.007</td>
<td>§205.6</td>
</tr>
<tr>
<td>53</td>
<td>74</td>
<td>93</td>
<td>152</td>
</tr>
<tr>
<td>499.03</td>
<td>499.72</td>
<td>61N-1.008</td>
<td>§205.8</td>
</tr>
<tr>
<td>56</td>
<td>74</td>
<td>94</td>
<td>152</td>
</tr>
<tr>
<td>499.032</td>
<td>499.73</td>
<td>61N-1.009</td>
<td>Chapter 9</td>
</tr>
<tr>
<td>56</td>
<td>74</td>
<td>95</td>
<td>157</td>
</tr>
<tr>
<td>499.033</td>
<td>499.74</td>
<td>61N-1.010</td>
<td>§321</td>
</tr>
<tr>
<td>56</td>
<td>75</td>
<td>95</td>
<td>157</td>
</tr>
<tr>
<td>499.035</td>
<td>499.75</td>
<td>61N-1.011</td>
<td>§331</td>
</tr>
<tr>
<td>57</td>
<td>75</td>
<td>97</td>
<td>178</td>
</tr>
<tr>
<td>499.036</td>
<td>499.76</td>
<td>61N-1.012</td>
<td>§333</td>
</tr>
<tr>
<td>57</td>
<td>76</td>
<td>99</td>
<td>195</td>
</tr>
<tr>
<td>499.039</td>
<td>499.77</td>
<td>61N-1.013</td>
<td>§351</td>
</tr>
<tr>
<td>59</td>
<td>76</td>
<td>106</td>
<td>210</td>
</tr>
<tr>
<td>499.04</td>
<td>499.78</td>
<td>61N-1.014</td>
<td>§352</td>
</tr>
<tr>
<td>59</td>
<td>76</td>
<td>110</td>
<td>214</td>
</tr>
<tr>
<td>499.041</td>
<td>499.79</td>
<td>61N-1.015</td>
<td>§353</td>
</tr>
<tr>
<td>59</td>
<td>76</td>
<td>111</td>
<td>229</td>
</tr>
</tbody>
</table>

**NOTE:** This booklet is intended to provide a direct access to Chapter 499, Florida Statutes, 61N-1, Florida Administrative Code and Parts of Title 21 of the Code of Federal Regulations and United States Code. This booklet is updated continually, but please reference the Florida Statutes and Administrative Code website before reviewing this booklet.
CHAPTER 499
FLORIDA DRUG AND COSMETIC ACT

PART I
DRUGS; DEVICES; COSMETICS; HOUSEHOLD PRODUCTS
(ss. 499.001-499.067)

PART II
ETHER
(ss. 499.601-499.79)

PART III
MEDICAL GAS
(ss. 499.81-499.94)

Chapter 499, Part I
DRUGS; DEVICES; COSMETICS; HOUSEHOLD PRODUCTS

499.001 Florida Drug and Cosmetic Act; short title.
499.002 Purpose, administration, and enforcement of and exemption from this part.
499.003 Definitions of terms used in this part.
499.005 Prohibited acts.
499.0051 Criminal acts.
499.0054 Advertising and labeling of drugs, devices, and cosmetics; exemptions.
499.006 Adulterated drug or device.
499.007 Misbranded drug or device.
499.008 Adulterated cosmetics.
499.009 Misbranded cosmetics.
499.01 Permits.
499.012 Permit application requirements.
499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.
499.0121 Storage and handling of prescription drugs; recordkeeping.
499.01211 Drug Wholesale Distributor Advisory Council.
499.015 Registration of drugs and devices; issuance of certificates of free sale.
499.023 New drugs; sale, manufacture, repackaging, distribution.
499.024 Drug product classification.
499.025 Drug products in finished, solid, oral dosage form; identification requirements.
499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.
499.029 Cancer Drug Donation Program.
499.0295 Experimental treatments for terminal conditions.
499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.
499.032 Phenylalanine; prescription required.
499.033 Ephedrine; prescription required.
499.035  Dimethyl sulfoxide (DMSO); labeling and advertising.
499.036  Restrictions on sale of dextromethorphan.
499.039  Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.
499.04  Fee authority.
499.041  Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.
499.05  Rules.
499.051  Inspections and investigations.
499.052  Records of interstate shipment.
499.055  Reports and dissemination of information by department.
499.057  Expenses and salaries.
499.06  Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.
499.062  Seizure and condemnation of drugs, devices, or cosmetics.
499.065  Inspections; imminent danger.
499.066  Penalties; remedies.
499.0661  Cease and desist orders; removal of certain persons.
499.067  Denial, suspension, or revocation of permit, certification, or registration.

499.001  Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.94 may be cited as the “Florida Drug and Cosmetic Act.”
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 1, ch. 86-133; ss. 1, 52, ch. 92-69; s. 122, ch. 2014-17; s. 1, ch. 2014-89.

499.002  Purpose, administration, and enforcement of and exemption from this part.—
(1)  This part is intended to:
(a)  Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.
(b)  Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.
(c)  Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.
(2)  The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.
(3)  For the purpose of any investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. The department shall exercise this power on its own initiative. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.
(4)  Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports any violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.
(5)  This part does not require the department to report, for the institution of proceedings under this part, minor violations of this part when it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.
(6)  Common carriers engaged in interstate commerce are not subject to this part if they are engaged in the usual course of business as common carriers.
Definitions of terms used in this part.—As used in this part, the term:

(1) “Active pharmaceutical ingredient” includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

(2) “Advertisement” means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) “Affiliate” means a business entity that has a relationship with another business entity in which, directly or indirectly:
   (a) The business entity controls, or has the power to control, the other business entity; or
   (b) A third party controls, or has the power to control, both business entities.

(4) “Affiliated party” means:
   (a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;
   (b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;
   (c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or
   (d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5) “Applicant” means a person applying for a permit or certification under this part.

(6) “Certificate of free sale” means a document prepared by the department which certifies a drug or device that is registered with the department as one that can be legally sold in the state.

(7) “Chain pharmacy warehouse” means a distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs between members of an affiliate.

(8) “Closed pharmacy” means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) “Color” includes black, white, and intermediate grays.

(10) “Color additive” means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:
   (a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or
   (b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11) “Contraband prescription drug” means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a transaction history, transaction information, or transaction statement does not exist, or for which the transaction history, transaction information, or transaction statement in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.
(12) “Cosmetic” means an article, with the exception of soap, that is:
(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or
(b) Intended for use as a component of any such article.
(13) “Counterfeit drug,” “counterfeit device,” or “counterfeit cosmetic” means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.
(14) “Department” means the Department of Business and Professional Regulation.
(15) “Device” means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:
(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,
(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or
(c) Intended to affect the structure or any function of the body of humans or other animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
(16) “Distribute” or “distribution” means to sell, purchase, trade, deliver, handle, store, or receive. The term does not mean to administer or dispense.
(17) “Drug” means an article that is:
(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;
(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
(c) Intended to affect the structure or any function of the body of humans or other animals; or
(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories.
(18) “Establishment” means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.
(20) “Freight forwarder” means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.
(21) “Health care entity” means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care
entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c.

(22) "Health care facility" means a health care facility licensed under chapter 395.

(23) "Hospice" means a corporation licensed under part IV of chapter 400.

(24) "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(25) "Immediate container" does not include package liners.

(26) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(27) "Labeling" means all labels and other written, printed, or graphic matters:
(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or
(b) Accompanying or related to such drug, device, or cosmetic.

(28) “Manufacture” means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(29) “Manufacturer” means:
(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics are not the subject of an approved application or license, the person who manufactured the drug or biologics;
(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph;
(c) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph; or
(d) A person who manufactures a device or a cosmetic.
The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(30) “Medical convenience kit” means packages or units that contain combination products as defined in 21 C.F.R. § 3.2(e)(2).

(31) “Medical gas” means any liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(32) “New drug” means:
(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or
(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(33) “Nursing home” means a facility licensed under part II of chapter 400.


(35) “Permittee” means any person holding a permit issued under this chapter.

(36) “Person” means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political
subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(37) “Pharmacist” means a person licensed under chapter 465.

(38) “Pharmacy” means an entity licensed under chapter 465.

(39) “Prepackaged drug product” means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(40) “Prescription drug” means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(41) “Prescription drug label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(42) “Prescription label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(43) “Proprietary drug,” or “OTC drug,” means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(44) “Repackage” includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(45) “Repackager” means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(46) “Retail pharmacy” means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(47) “Veterinary prescription drug” means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, “Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian.”

(48) “Wholesale distribution” means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(h):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The distribution of a prescription drug or an offer to distribute a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution of a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, “common control” means the power
to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The distribution of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the distribution of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The distribution of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution of a prescription drug or offer to distribute a prescription drug for emergency medical reasons, which may include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.
6. The distribution of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes prescription drugs pursuant to this subparagraph must reconcile all drugs distributed and returned and resolve any discrepancies in a timely manner.

(c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the prescription drug.

(e) The distribution of prescription drug samples by manufacturers’ representatives or distributors’ representatives conducted in accordance with s. 499.028.

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times.

(j) The distribution of blood and blood components intended for transfusion. As used in this paragraph, the term “blood” means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term “blood components” means that part of the blood separated by physical or mechanical means.

(k) The lawful dispensing of a prescription drug in accordance with chapter 465.

(l) The distribution of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder. The department shall adopt rules specifying the quantities of prescription drugs which are considered to be minimal quantities. However, until such rules are adopted, minimal quantities distributed may not exceed 3 percent of the retail pharmacy’s total annual purchases of prescription drugs.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).
A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

Saleable drug returns when conducted by a dispenser.

Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;
2. A health care clinic establishment permitted pursuant to this chapter; or
3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health, if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

The distribution of medical gas pursuant to part III of this chapter.

“Wholesale distributor” means a person, other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution.

It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

1. The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.
2. The adulteration or misbranding of any drug, device, or cosmetic.
3. The receipt of any drug, device, or cosmetic in violation of this part.
4. The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.
5. The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.
6. The refusal or constructive refusal:
   a. To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;
   b. To allow inspection of any record of that establishment;
(c) To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or
(d) To allow the department to take samples of any drug, device, or cosmetic.
(7) The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103.
(8) Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.
(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.
(10) Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.
(11) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.
(12) The possession of any drug in violation of this part.
(13) The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.
(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.
(15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.
(16) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.
(17) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.
(18) Failure to maintain records as required by this part and rules adopted under this part.
(19) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part.
(20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.
(21) The wholesale distribution of any prescription drug that was:
(a) Purchased by a public or private hospital or other health care entity; or
(b) Donated or supplied at a reduced price to a charitable organization, unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c.
(22) Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.
(23) Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.
(24) The distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.
(25) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.
(26) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27) Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement as required under this part and rules adopted under this part.

History.—s. 34, ch. 82-225; s. 106, ch. 83-218; s. 1, ch. 83-265; s. 24, ch. 88-380; ss. 5, 52, ch. 92-69; s. 3, ch. 95-308; s. 585, ch. 97-103; s. 29, ch. 98-151; s. 37, ch. 99-397; s. 35, ch. 2000-242; s. 17, ch. 2001-63; s. 32, ch. 2001-89; s. 4, ch. 2003-155; s. 4, ch. 2006-310; s. 21, ch. 2007-6; s. 48, ch. 2008-177; s. 3, ch. 2008-207; s. 3, ch. 2012-37; s. 3, ch. 2016-212.

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—

(a) A person engaged in the distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the distribution of prescription drugs who fails to acquire a complete and accurate transaction history, transaction information, or transaction statement concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION DRUG FROM UNAUTHORIZED PERSON.—A person who knowingly purchases or receives from a person not authorized to distribute prescription drugs under this chapter a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) KNOWING SALE OR TRANSFER OF PRESCRIPTION DRUG TO UNAUTHORIZED PERSON.—A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND PRESCRIPTION DRUGS.—A person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or
who possesses with intent to sell or deliver any amount of contraband prescription drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION DRUGS.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:
   1. If the value of contraband prescription drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.
   2. If the value of contraband prescription drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.
   3. If the value of contraband prescription drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b) As used in this subsection, the term “value” means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription drugs involved in distinct transactions for the distribution of the contraband prescription drugs committed pursuant to one scheme or course of conduct, whether involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(7) KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION DRUG LABELS.—A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription drug label, or who falsely represents any factual matter contained on any prescription label or prescription drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(8) KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN GREAT BODILY HARM.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(9) KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN DEATH.—A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10) VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—
    (a) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except
that any person who violates s. 499.005(8) or (10) with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

(b) A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(11) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) The adulteration or misbranding of any drug intended for further distribution.

(c) The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d) The dissemination of any false or misleading advertisement of a drug.

(e) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(f) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements.

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a) The refusal or constructive refusal to allow:
   1. The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;
   2. Inspection of any record of that establishment;
   3. The department to enter and inspect any vehicle that is being used to transport drugs; or
   4. The department to take samples of any drug.

(b) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part related to a drug.
(d) The failure to receive, maintain, or provide invoices and shipping documents if applicable, related to the distribution of a prescription drug.
(e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.
(f) The wholesale distribution of a prescription drug that was:
1. Purchased by a public or private hospital or other health care entity; or
2. Donated or supplied at a reduced price to a charitable organization.
(g) The failure to obtain a permit as a prescription drug wholesale distributor when a permit is required by this part for that activity.
(h) Knowingly possessing any adulterated or misbranded prescription drug outside of a designated quarantine area.
(i) The purchase or sale of a prescription drug for wholesale distribution in exchange for currency, as defined in s. 560.103.

(13) OTHER VIOLATIONS.—Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:
(a) Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.
(b) Knowingly adulterating a drug that is intended for further distribution.
(c) Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.
(d) Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.
(e) Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.
(f) Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.
(g) Removing a pharmacy’s dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.
(h) Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(14) FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (11), subsection (12), or subsection (13) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

(15) FALSE REPORT.—Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(16) CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times
the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

History.—s. 34, ch. 82-225; s. 118, ch. 83-218; s. 1, ch. 83-265; ss. 47, 52, ch. 92-69; s. 595, ch. 97-103; s. 40, ch. 99-397; ss. 5, 6, 7, 8, 27, 28, ch. 2003-155; s. 16, ch. 2007-6; s. 49, ch. 2008-177; s. 4, ch. 2008-207; s. 16, ch. 2011-141; s. 4, ch. 2016-212.

Note.—Subsection (7) former s. 499.0052; subsection (9) former s. 499.00535; subsection (10) former s. 499.00545; subsection (11) former s. 499.0069; subsections (12)-(15) former s. 499.0691.

499.0054 Advertising and labeling of drugs, devices, and cosmetics; exemptions.—
(1) It is a violation of the Florida Drug and Cosmetic Act to perform or cause the performance of any of the following acts:
(a) The dissemination of any false advertisement of any drug, device, or cosmetic. An advertisement is false if it is false or misleading in any way.
(b) The distribution in commerce of any drug, device, or cosmetic, if its labeling or advertising is in violation of this part.
(c) The manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of any drug, device, or cosmetic for which the advertising or labeling is false or misleading.
(d) The advertising of any drug, device, or cosmetic that is adulterated or misbranded.
(e) The receiving in commerce of any drug, device, or cosmetic that is falsely advertised or labeled or the delivering or proffering for delivery of any such drug, device, or cosmetic.
(f) The advertising or labeling of any product containing ephedrine, a salt of ephedrine, an isomer of ephedrine, or a salt of an isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indications not approved by the pertinent United States Food and Drug Administration Over-the-Counter Final or Tentative Final Monograph or approved new drug application under the federal act. In determining compliance with this requirement, the department may consider the following factors:
1. The packaging of the product.
2. The name and labeling of the product.
3. The manner of distribution, advertising, and promotion of the product, including verbal representations at the point of sale.
4. The duration, scope, and significance of abuse of the particular product.
(g) The advertising of any drug or device represented to have any effect in any of the following conditions, disorders, diseases, or processes:
2. Bone or joint diseases.
3. Kidney diseases or disorders.
5. Diabetes.
6. Gall bladder diseases or disorders.
7. Heart and vascular diseases.
8. High blood pressure.
9. Diseases or disorders of the ear or auditory apparatus, including hearing loss or deafness.
10. Mental disease or intellectual disability.
11. Paralysis.
12. Prostate gland disorders.
13. Conditions of the scalp affecting hair loss.
15. Endocrine disorders.
17. Tumors.
18. Venereal diseases.
22. Metabolic disorders.
23. Immune system disorders or conditions affecting the immune system.
25. Stress and tension.
27. The body’s natural defense mechanisms.
29. Depression.
30. Human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions.

(h) The representation or suggestion in labeling or advertising that an article is approved under this part, when such is not the case.

(2) In determining whether an advertisement is false or misleading, the department shall review the representations made or suggested by statement, word, design, device, sound, or any combination thereof within the advertisement and the extent to which the advertisement fails to reveal material facts with respect to consequences that can result from the use of the drug, device, or cosmetic to which the advertisement relates under the conditions of use prescribed in the labeling or advertisement.

(3)(a) An advertisement that is not prohibited under paragraph (1)(a) is not prohibited under paragraph (1)(g) if it is disseminated:
1. To the public solely to advertise the product for those indications that are safe and effective indications and the product is safe and effective for self-medication, as established by the United States Food and Drug Administration; or
2. Only to members of the medical, dental, pharmaceutical, or veterinary professions or appears only in the scientific periodicals of these professions.

(b) Compliance with this part and the rules adopted under this part creates no legal presumption that a drug or device is safe or effective.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 1, 2, 4, ch. 86-271; s. 5, ch. 88-172; s. 25, ch. 88-380; ss. 7, 8, 9, 52, ch. 92-69; ss. 2, 3, ch. 95-415; s. 36, ch. 2000-242; s. 5, ch. 2008-207; s. 17, ch. 2013-162.
Note.—Subsection (2) former s. 499.0055; subsection (3) former s. 499.0057.

499.006 Adulterated drug or device.—A drug or device is adulterated, if any of the following apply:
(1) It consists in whole or in part of any filthy, putrid, or decomposed substance.
(2) It has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health.
(3) It is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess.
(4) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health.
(5) It is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act.
(6) It purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label.

(7) It is not subject to subsection (6) and its strength differs from, or its quality or purity falls below the standard of, that which it purports or is represented to possess.

(8) It is a drug:
(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or
(b) For which any substance has been substituted wholly or in part.

(9) It is a drug or device for which the expiration date has passed.

(10) It is a prescription drug for which the required transaction history, transaction information, or transaction statement is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

(11) It is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 10, 52, ch. 92-69; s. 9, ch. 2003-155; s. 1, ch. 2006-92; s. 6, ch. 2008-207; s. 5, ch. 2016-212.

499.007 Misbranded drug or device.—A drug or device is misbranded:
(1) If its labeling is in any way false or misleading.
(2) If in package form, it does not bear a label containing:
(a) The name and place of business of the manufacturer, repackager, or distributor of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a prescription drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, and labeling; and
(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, under this section, reasonable variations are permitted, and the department shall establish by rule exemptions for small packages.
(3) If it is an active pharmaceutical ingredient in bulk form and does not bear a label containing:
(a) The name and place of business of the manufacturer, repackager, or distributor; and
(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
(4) If any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.
(5) If it is a drug and is not designated solely by a name recognized in an official compendium and its label does not bear:
(a) The common or usual name of the drug, if any; and
(b) In case it is fabricated from two or more ingredients, the common or usual name and quantity of each active ingredient.

(6) If its labeling does not bear:
(a) Adequate directions for use; and
(b) Adequate warnings against use in those pathological conditions in which its use may be dangerous to health or against use by children if its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

(7) If it purports to be a drug the name of which is recognized in the official compendium and it is not packaged and labeled as prescribed therein. However, the method of packaging may be modified with the consent of the department.

(8) If it has been found by the department to be a drug liable to deterioration and it is not packaged in such form and manner, and its label bears a statement of such precautions, as the department by rule requires as necessary to protect the public health. Such rule may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and that body has failed within a reasonable time to prescribe such requirements.

(9) If it is:
(a) A drug and its container or finished dosage form is so made, formed, or filled as to be misleading;
(b) An imitation of another drug; or
(c) Offered for sale under the name of another drug.

(10) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.

(11) If it is, purports to be, or is represented as a drug composed wholly or partly of insulin and it is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which certificate is in effect with respect to the drug.

(12) If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which certificate is in effect with respect to the drug. However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

(13) If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, if it is not dispensed only:
(a) Upon the written prescription of a practitioner licensed by law to prescribe such drug;
(b) Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or
(c) By refilling any such written or oral prescription, if such refilling is authorized by the prescriber in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(14) If it is a drug that is subject to paragraph (13)(a), and if, at any time before it is dispensed, its label does not bear the statement:
(a) “Caution: Federal Law Prohibits Dispensing Without Prescription”;
(b) “Rx Only”;
(c) The prescription symbol followed by the word “Only”; or
(d) “Caution: State Law Prohibits Dispensing Without Prescription.”
(15) If it is a drug that is not subject to paragraph (13)(a), if at any time before it is dispensed its label bears the statement of caution required in subsection (14).
(16) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only and its packaging and labeling are not in conformity with the packaging and labeling requirements that apply to such color additive and are prescribed under the federal act.
(17) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (9), (11), and (12) and the packaging requirements of subsections (7) and (8), if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (13). The department may, by rule, exempt drugs subject to s. 499.062 from subsection (13) if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

499.008 Adulterated cosmetics.—A cosmetic is adulterated:
(1) If it bears or contains any poisonous or deleterious substance that is injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual; however, this subsection does not apply to coal-tar hair dye:
(a) The label of which bears the following legend conspicuously displayed thereon: “Caution: This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness”; and
(b) The labeling of which bears adequate directions for such preliminary testing.
(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.
(3) If it has been produced, prepared, packed, or held under conditions whereby it could have become contaminated with filth or whereby it could have been rendered injurious to health.
(4) If it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of the federal act.
(5) For the purposes of subsections (1) and (4), the term “hair dye” does not include eyelash dyes or eyebrow dyes.

499.009 Misbranded cosmetics.—A cosmetic is misbranded:
(1) If its labeling is false or misleading in any particular.
(2) If in package form, it does not bear a label containing:
(a) The name and place of business of the manufacturer, packer, or distributor;
(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; however, under this paragraph reasonable variations are permitted, and the department shall establish by rule exemptions for small packages; and
(c) A declaration of ingredients in descending order of predominance, or as otherwise required by federal law.
(3) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as
compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood by an individual under customary conditions of purchase and use.

(4) If its container is so made, formed, or filled as to be misleading.

(5) If it is a color additive, its packaging and labeling are not in conformity with the packaging and labeling requirements applicable to that color additive prescribed under the federal act. This subsection does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 13, 52, ch. 92-69; s. 9, ch. 2008-207.

499.01 Permits.—

(1) Before operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;
(b) A prescription drug repackager;
(c) A nonresident prescription drug manufacturer;
(d) A nonresident prescription drug repackager;
(e) A prescription drug wholesale distributor;
(f) An out-of-state prescription drug wholesale distributor;
(g) A retail pharmacy drug wholesale distributor;
(h) A restricted prescription drug distributor;
(i) A complimentary drug distributor;
(j) A freight forwarder;
(k) A veterinary prescription drug retail establishment;
(l) A veterinary prescription drug wholesale distributor;
(m) A limited prescription drug veterinary wholesale distributor;
(n) An over-the-counter drug manufacturer;
(o) A device manufacturer;
(p) A cosmetic manufacturer;
(q) A third party logistics provider; or
(r) A health care clinic establishment.

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in distribution of prescription drugs for which the person is the manufacturer and must comply with s. 499.0121 and all other provisions of this part and rules adopted under this part. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.
1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(d) Nonresident prescription drug repackager permit.—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.

2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(e) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.
the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and rules adopted under this part.
2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.
3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.
4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.
5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(h) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:
   a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered “wholesale distribution” under s. 499.003(48)(a).
   b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.
   c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner’s order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:
      (I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;
      (II) Blood-collection containers approved under s. 505 of the federal act;
      (III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;
      (IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or
      (V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting,
processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

(i) Complimentary drug distributor permit.—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(j) Freight forwarder permit.—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(k) Veterinary prescription drug retail establishment permit.—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner’s order may not be returned into the retail establishment’s inventory.

(l) Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of
veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale
distributor that also distributes prescription drugs subject to, defined by, or described by s.
503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a
permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale
distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary
prescription drug wholesale distributor permit. A veterinary prescription drug wholesale
distributor must comply with the requirements for wholesale distributors under s. 499.0121.
(m) Limited prescription drug veterinary wholesale distributor permit.—Unless engaging in the
activities of and permitted as a prescription drug manufacturer, nonresident prescription drug
manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale
distributor, a limited prescription drug veterinary wholesale distributor permit is required for any
person that engages in the distribution in or into this state of veterinary prescription drugs and
prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug,
and Cosmetic Act under the following conditions:
1. The person is engaged in the business of wholesaling prescription and veterinary
prescription drugs to persons:
   a. Licensed as veterinarians practicing on a full-time basis;
   b. Regularly and lawfully engaged in instruction in veterinary medicine;
   c. Regularly and lawfully engaged in law enforcement activities;
   d. For use in research not involving clinical use; or
   e. For use in chemical analysis or physical testing or for purposes of instruction in law
      enforcement activities, research, or testing.
2. No more than 30 percent of total annual prescription drug sales may be prescription drugs
   approved for human use which are subject to, defined by, or described by s. 503(b) of the
3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by,
   or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is
   authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.
4. A limited prescription drug veterinary wholesale distributor that applies to the department for
   a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent
   means of security acceptable to the department, such as an irrevocable letter of credit or a
   deposit in a trust account or financial institution, payable to the Professional Regulation Trust
   Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by
   the department and any fees and costs incurred by the department regarding that permit which
   are authorized under state law and which the permittee fails to pay 30 days after the fine or
   costs become final. The department may make a claim against such bond or security until 1
   year after the permittee’s license ceases to be valid or until 60 days after any administrative or
   legal proceeding authorized in this part which involves the permittee is concluded, including any
   appeal, whichever occurs later.
5. A limited prescription drug veterinary wholesale distributor must maintain at all times a
   license or permit to engage in the wholesale distribution of prescription drugs in compliance with
   laws of the state in which it is a resident.
6. A limited prescription drug veterinary wholesale distributor must comply with the
   requirements for wholesale distributors under s. 499.0121.
7. A limited prescription drug veterinary wholesale distributor may not return to inventory for
   subsequent wholesale distribution any prescription drug subject to, defined by, or described by
   s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a
   veterinarian.
8. A limited prescription drug veterinary wholesale distributor permit is not required for an
   intracompany sale or transfer of a prescription drug from an out-of-state establishment that is
duly licensed to engage in the wholesale distribution of prescription drugs in its state of
residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

(n) Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.
1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.
2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.
3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(o) Device manufacturer permit.—
1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:
   a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner’s order for a specific patient; or
   b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).
2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.
3. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(p) Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(q) Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, wholesale distributor, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with s. 499.0121 and other rules that the department requires.

(r) Health care clinic establishment permit.—A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term “qualifying practitioner” means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.
1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the
prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6). The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: “Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale.”

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.
1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6).

(b) A permit issued under this part is not required to distribute a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6).

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: “Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale.”

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:
   1. A record of the FDA establishment registration number, if any;
   2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs; and
   3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing
within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permit holder that is a health care entity to repackaging prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3., if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The department shall adopt rules to ensure the safety and integrity of prescription drugs repackaged and distributed under this subsection, including rules regarding prescription drug manufacturing and labeling requirements.

499.012 Permits application requirements.—

(1)(a) A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly
or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy does not meet the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant to this part.

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and that the applicant has failed to cure the deficiency, the application shall expire. The determination
regarding the 2-year lapse of time shall be based on documentation that the department notified
the applicant of the deficiency in accordance with s. 120.60.
(c) Information submitted by an applicant on an application required pursuant to this
subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the
department as trade secret information pursuant to s. 499.051(7).
(4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state
prescription drug wholesale distributor, an application for a permit must include:
1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. The address, telephone numbers, and the names of contact persons for each facility used
by the applicant for the storage, handling, and distribution of prescription drugs;
4. The type of ownership or operation, such as a partnership, corporation, or sole
proprietorship; and
5. The names of the owner and the operator of the establishment, including:
a. If an individual, the name of the individual;
b. If a partnership, the name of each partner and the name of the partnership;
c. If a corporation, the name and title of each corporate officer and director, the corporate
names, and the name of the state of incorporation;
d. If a sole proprietorship, the full name of the sole proprietor and the name of the business
entity;
e. If a limited liability company, the name of each member, the name of each manager, the
name of the limited liability company, and the name of the state in which the limited liability
company was organized; and
f. Any other relevant information that the department requires.
(b) Upon approval of the application by the department and payment of the required fee, the
department shall issue a permit to the applicant, if the applicant meets the requirements of this
part and rules adopted under this part.
(c) Any change in information required under paragraph (a) must be submitted to the
department before the change occurs.
(d) The department shall consider, at a minimum, the following factors in reviewing the
qualifications of persons to be permitted under this part:
1. The applicant’s having been found guilty, regardless of adjudication, in a court of this state
or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A
plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.
2. The applicant’s having been disciplined by a regulatory agency in any state for any offense
that would constitute a violation of this part.
3. Any felony conviction of the applicant under a federal, state, or local law;
4. The applicant’s past experience in manufacturing or distributing drugs, devices, or
cosmetics;
5. The furnishing by the applicant of false or fraudulent material in any application made in
connection with manufacturing or distributing drugs, devices, or cosmetics;
6. Suspension or revocation by a federal, state, or local government of any permit currently or
previously held by the applicant for the manufacture or distribution of any drugs, devices, or
cosmetics;
7. Compliance with permitting requirements under any previously granted permits;
8. Compliance with requirements to maintain or make available to the state permitting
authority or to federal, state, or local law enforcement officials those records required under this
section; and
9. Any other factors or qualifications the department considers relevant to and consistent with
the public health and safety.
The department shall adopt rules for the biennial renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and rules adopted under this part.

At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.

A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45 days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4. Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1. Return the permit to the department;
2. If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part.
Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the licensed premises.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.
(b) All trade or business names used by the applicant.
(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.
(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:
   1. If an individual, the name of the individual.
   2. If a partnership, the name of each partner and the name of the partnership.
   3. If a corporation:
      a. The name, address, and title of each corporate officer and director.
      b. The name and address of the corporation, resident agent of the corporation, the resident agent’s address, and the corporation’s state of incorporation.
      c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.
   4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
   5. If a limited liability company:
      a. The name and address of each member.
      b. The name and address of each manager.
      c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of the applicant.

(g) The applicant’s gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year.

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant’s establishment is located, if the establishment is owned by the applicant, or a copy of the applicant’s lease for the property on which applicant’s establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant’s designated representatives as required by subsection (15), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant’s previous tax year are $10
million or less, evidence of a surety bond in the amount of $25,000. The specific language of the
surety bond must include the State of Florida as a beneficiary, payable to the Professional
Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent
security such as an irrevocable letter of credit, or a deposit in a trust account or financial
institution, which includes the State of Florida as a beneficiary, payable to the Professional
Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any
administrative penalties imposed by the department and any fees and costs incurred by the
department regarding that permit which are authorized under state law and which the permittee
fails to pay 30 days after the fine or costs become final. The department may make a claim
against such bond or security until 1 year after the permittee’s license ceases to be valid or until
60 days after any administrative or legal proceeding authorized in this part which involves the
permittee is concluded, including any appeal, whichever occurs later.

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal
information statement and fingerprints shall provide the following information to the department:
1. The person’s places of residence for the past 7 years.
2. The person’s date and place of birth.
3. The person’s occupations, positions of employment, and offices held during the past 7
   years.
4. The principal business and address of any business, corporation, or other organization in
   which each such office of the person was held or in which each such occupation or position of
   employment was carried on.
5. Whether the person has been, during the past 7 years, the subject of any proceeding for the
   revocation of any license and, if so, the nature of the proceeding and the disposition of the
   proceeding.
6. Whether, during the past 7 years, the person has been enjoined, temporarily or
   permanently, by a court of competent jurisdiction from violating any federal or state law
   regulating the possession, control, or distribution of prescription drugs, together with details
   concerning any such event.
7. A description of any involvement by the person with any business, including any
   investments, other than the ownership of stock in a publicly traded company or mutual fund,
   during the past 4 years, which manufactured, administered, prescribed, distributed, or stored
   pharmaceutical products and any lawsuits in which such businesses were named as a party.
8. A description of any felony criminal offense of which the person, as an adult, was found
   guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty
   or nolo contendere. A criminal offense committed in another jurisdiction which would have been
   a felony in this state must be reported. If the person indicates that a criminal conviction is under
   appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must,
within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9. A photograph of the person taken in the previous 180 days.

10. A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11. The name, address, occupation, and date and place of birth for each member of the person’s immediate family who is 18 years of age or older. As used in this subparagraph, the term “member of the person’s immediate family” includes the person’s spouse, children, parents, siblings, the spouses of the person’s children, and the spouses of the person’s siblings.

12. Any other relevant information that the department requires.

(b) The information required pursuant to paragraph (a) shall be provided under oath.

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person.

Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph is not required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of an applicant after January 1, 2004. The department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (16), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant’s past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.
The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

The applicant for renewal of a permit under s. 499.01(2)(e) or (f) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

Information obtained in response to s. 499.01(2)(e) or (f) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor’s permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:
1. The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;
2. The pharmacy maintains its permit under chapter 465;
3. The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of s. 499.0121 with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;
4. The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;
5. Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and
6. The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b) A wholesale distributor’s permit is not required for the one-time transfer of title of a pharmacy’s lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy’s inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13) Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(14) The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:
1. Submit an application on a form furnished by the department and pay the appropriate fees.
2. Be at least 18 years of age.
3. Have at least 2 years of verifiable full-time:
   a. Work experience in a pharmacy licensed in this state or another state, where the person’s responsibilities included, but were not limited to, recordkeeping for prescription drugs;
   b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or
   c. Managerial experience with the United States Armed Forces, where the person’s responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.
4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.
5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).
   (c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.
   (d) A designated representative:
      1. Must be actively involved in and aware of the actual daily operation of the wholesale distributor.
      2. Must be employed full time in a managerial position by the wholesale distributor.
      3. Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.
      4. May serve as a designated representative for only one wholesale distributor at any one time.
   (e) A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative’s employment with the wholesale distributor.
   (f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.


Note.—Redesignated as subsection (15) by s. 7, ch. 2016-212.

Note.—Subsections (1)-(7) former s. 499.01(2)-(8).

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision of law, the Agency for Health Care Administration may not:
499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(1) ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:
   (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
   (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   (c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
   (d) Be maintained in a clean and orderly condition; and
   (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) SECURITY.—
   (a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.
   1. Access from outside the premises must be kept to a minimum and be well controlled.
   2. The outside perimeter of the premises must be well lighted.
   3. Entry into areas where prescription drugs are held must be limited to authorized personnel.
   (b) An establishment that is used for wholesale drug distribution must be equipped with:
       1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers; and
       2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
   (c) Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(3) STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.
   (a) If no storage requirements are established for a prescription drug, the drug may be held at “controlled” room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
   (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.
   (c) The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4) EXAMINATION OF MATERIALS AND RECORDS.—
   (a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for
distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug’s safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug’s safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) The following persons must maintain business records that include the information specified in paragraph (b):

1. Persons permitted or required to be permitted under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs.

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs.

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.
4. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.
5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.
6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.
7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug.

(c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:
1. The name and address of the seller or transferor of the product.
2. The address of the location the product was shipped from.
3. The date of the sale or distribution of the product.
4. The name and quantity of the product involved.
5. The name and address of the person who purchased the product.

(d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for inspection by the department within 2 business days.

(e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part, and such records must be readily available for inspection.

(f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.

(g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

7) PRESCRIPTION DRUG PURCHASE LIST.—
(a) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list.
(b) Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.
(8) WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.
2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or
3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9) RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(11) SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(12) SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting
prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor’s licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale distributor’s Florida permit is valid.

(e) Inspect the selling wholesale distributor’s licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or
2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:
(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity’s clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity’s clinical needs to determine whether violations of chapter 893 have occurred.

15) DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.
2. A review of the receiving entity’s history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.
3. A determination that the receiving entity’s Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity’s clinical business needs.

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity’s clinical business needs, location, and population served, in addition to other factors established in the distributor’s policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.
499.011 Drug Wholesale Distributor Advisory Council.—
(1) There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint 10 additional members to the council who shall be appointed to a term of 4 years each, as follows:
(a) Three persons, each of whom is employed by a different prescription drug wholesale distributor permitted under this part which operates nationally and is a primary wholesale distributor as defined in s. 499.003.
(b) One person employed by a prescription drug wholesale distributor permitted under this part which is a secondary wholesale distributor, as defined in s. 499.003.
(c) One person employed by a retail pharmacy chain located in this state.
(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.
(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.
(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.
(g) One person who is an employee of a pharmaceutical manufacturer.
(h) One person who is an employee of a permitted medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

(3) The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states’ regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

499.015 Registration of drugs and devices; issuance of certificates of free sale.—
(1) (a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.
(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the...
department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or device to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer’s medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;
(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or
(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21; s. 36, ch. 2014-89; s. 10, ch. 2016-212; s. 33, ch. 2017-3; s. 1, ch. 2017-51.

499.023 New drugs; sale, manufacture, repackaging, distribution.—A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 26, 52, ch. 92-69.

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.
(1) Drug products must be classified as proprietary, prescription, or investigational drugs.
(2) If a product is distributed without required labeling, it is misbranded while held for sale.
(3) Any product that falls under the definition of drug in s. 499.003 may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.
(4) Any product classified under the authority of this section reverts to the federal classification, if different, upon the federal regulation or act becoming effective.
(5) The department may by rule reclassify drugs subject to this part when such classification action is necessary to protect the public health.
(6) The department may adopt rules that exempt from any labeling or packaging requirements of this part drugs classified under this section if those requirements are not necessary to protect the public health.

History.—s. 9, ch. 88-159; s. 1, ch. 89-296; ss. 27, 52, ch. 92-69; s. 589, ch. 97-103; s. 42, ch. 2000-242; s. 13, ch. 2000-326; s. 61, ch. 2006-1; s. 106, ch. 2008-6; s. 19, ch. 2008-207; s. 5, ch. 2012-143; s. 37, ch. 2014-89.

499.025 Drug products in finished, solid, oral dosage form; identification requirements.—
(1) A drug product in finished, solid, oral dosage form for which a prescription is required by federal or state law may not be manufactured or distributed within this state unless it is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, or national drug code, or any combination thereof, that identifies the drug product and the manufacturer or distributor of the drug product which has the ability to respond to requests for information regarding the drug product.
(2) A manufacturer or distributor must make available to the department on request descriptive material that identifies each current imprint used by the manufacturer.
(3) The department, upon application by a manufacturer, may exempt a particular drug product from the requirements of subsection (1) on the ground that imprinting is not feasible because of the size, texture, or other unique characteristic of the drug product.
(4) This section does not apply to drug products compounded by a pharmacist licensed under chapter 465 in a pharmacy operating under a permit issued by the Board of Pharmacy.
The department shall adopt rules for implementing this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 22, ch. 86-256; ss. 28, 52, ch. 92-69; s. 18, ch. 2000-326.

499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.—

(1) As used in this section, the term:
   (a) “Drug sample,” or “complimentary drug,” means a human prescription drug that is labeled “sample,” “not to be sold,” “complimentary,” or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.
   (b) “Starter packs,” also known as “stock samples,” “trade packages,” “initial dose packs,” or “starter stocks,” means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2) A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3) Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.
   (a) The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:
      1. In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and
      2. Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.
   (b) A written request for a drug sample that is required by this section must contain:
      1. The name, address, professional designation, and signature of the practitioner who makes the request;
      2. The name, strength, and dosage form of the drug sample requested and the quantity requested;
      3. The name of the manufacturer of the drug sample requested; and
      4. The date of the request.
   (c) Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.
   (d) The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).
   (e) Drug samples may only be distributed:
      1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or
2. At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner’s name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

(4) A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.

(5) A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under 1 subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.

(6) A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.

(7) A drug manufacturer or distributor must report to the department any conviction of itself or of its employees, agents, or representatives for a violation of s. 503(c)(1) of the federal act or of this part because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(8) Drug manufacturers or distributors must provide to the department the name and telephone number of the individual responsible for responding to a request for information regarding drug samples.

(9) All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10) A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a) Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding $250 per year, as is determined by the department.

(b) A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c) A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal fee of not more than $250 per year, as determined by the department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12) The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a) Such permit was obtained by misrepresentation or fraud or through a mistake of the department.
(b) The holder of the permit has distributed or disposed of any prescription drug, directly or through its agents, employees, or independent contractors, to any person not authorized to possess such drug.
(c) The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription drug except in the usual course of its business.
(d) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug that is misbranded or adulterated under this part.
(e) The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug without written request, when a written request is required by this section.
(f) The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:
   1. Violated the requirements of this section or any rule adopted under this section.
   2. Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13) The department may, pursuant to chapter 120, impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be deposited into the Professional Regulation Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:
   (a) The severity of the violation.
   (b) Any actions taken by the permittee to correct the violation or to remedy complaints.
   (c) Any previous violations.
   (14) Chapter 893 applies to all drug samples that are controlled substances.
   (15) A person may not possess a prescription drug sample unless:
      (a) The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(4).
      (b) She or he is the employee of a complimentary drug distributor that holds a permit issued under this part.
      (c) She or he is a person to whom prescription drug samples may be distributed pursuant to this section.
      (d) He or she is an officer or employee of a federal, state, or local government acting within the scope of his or her employment.

History.—s. 34, ch. 82-225; s. 114, ch. 83-218; s. 1, ch. 83-265; s. 8, ch. 84-115; s. 23, ch. 86-256; ss. 29, 52, ch. 92-69; s. 198, ch. 94-218; s. 23, ch. 97-98; s. 590, ch. 97-103; s. 39, ch. 99-397; s. 20, ch. 2008-207; s. 12, ch. 2012-143; s. 34, ch. 2016-230.
1Note.—Subsection (5) does not contain subparagraphs.

499.029 Cancer Drug Donation Program.—
(1) This section may be cited as the “Cancer Drug Donation Program Act.”
(2) There is created a Cancer Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.
(3) As used in this section:
   (a) “Cancer drug” means a prescription drug that has been approved under s. 505 of the Federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. “Cancer drug” does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.
(b) “Closed drug delivery system” means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.
(c) “Donor” means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.
(d) “Eligible patient” means a person who the department determines is eligible to receive cancer drugs from the program.
(e) “Participant facility” means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.
(f) “Prescribing practitioner” means a physician licensed under chapter 458 or chapter 459 or any other medical professional with authority under state law to prescribe cancer medication.
(g) “Program” means the Cancer Drug Donation Program created by this section.
(h) “Supplies” means any supplies used in the administration of a cancer drug.
(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.
(5) The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.
(6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.
(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).
(c) Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.
(d) A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.
(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.
(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility’s name, address, and telephone number. The department shall make the participant facility registry available on the department’s website to any donor wishing to donate cancer drugs or supplies to the program. The department’s website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

History.—s. 1, ch. 2006-310; s. 122, ch. 2007-5; ss. 2, 21, ch. 2008-207; s. 23, ch. 2016-105.

499.0295 Experimental treatments for terminal conditions.—

(1) This section may be cited as the “Right to Try Act.”

(2) As used in this section, the term:

(a) “Eligible patient” means a person who:
1. Has a terminal condition that is attested to by the patient’s physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition;
2. Has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration;
3. Has given written informed consent for the use of an investigational drug, biological product, or device; and
4. Has documentation from his or her treating physician that the patient meets the requirements of this paragraph.

1(b) “Investigational drug, biological product, or device” means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(c) “Terminal condition” means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

(d) “Written informed consent” means a document that is signed by a patient, a parent of a minor patient, a court-appointed guardian for a patient, or a health care surrogate designated by a patient and includes:
1. An explanation of the currently approved products and treatments for the patient’s terminal condition.
2. An attestation that the patient concurs with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient’s life.
3. Identification of the specific investigational drug, biological product, or device that the patient is seeking to use.
4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment. The description shall be based on the physician’s knowledge of the proposed treatment for the patient’s terminal condition.
5. A statement that the patient’s health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless required to do so by law or contract.
6. A statement that the patient’s eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements.
7. A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient’s estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

1(3) Upon the request of an eligible patient, a manufacturer may:
(a) Make its investigational drug, biological product, or device available under this section.
(b) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.
(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.
(4) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of, or the cost of services related to the use of, an investigational drug, biological product, or device.

(5) A hospital or health care facility licensed under chapter 395 is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

(6) If an eligible patient dies while using an investigational drug, biological product, or device pursuant to this section, the patient’s heirs are not liable for any outstanding debt related to the patient’s use of the investigational drug, biological product, or device.

(7) A licensing board may not revoke, fail to renew, suspend, or take any action against a physician’s license issued under chapter 458 or chapter 459 based solely on the physician’s recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. A state entity responsible for Medicare certification may not take action against a physician’s Medicare certification based solely on the physician’s recommendation that an eligible patient have access to an investigational drug, biological product, or device.

(8) This section does not create a private cause of action against the manufacturer of an investigational drug, biological product, or device; against a person or entity involved in the care of an eligible patient who is using the investigational drug, biological product, or device; or for any harm to the eligible patient that is a result of the use of the investigational drug, biological product, or device if the manufacturer or other person or entity complies in good faith with the terms of this section and exercises reasonable care.

(9) This section does not expand the coverage an insurer must provide under the Florida Insurance Code and does not affect mandatory health coverage for participation in clinical trials.

History.—s. 1, ch. 2015-107; s. 2, ch. 2016-123; ss. 1, 9, ch. 2017-232.

1Note.—Section 1, ch. 2017-232, provides that “[i]t is the intent of the Legislature to implement s. 29, Article X of the State Constitution by creating a unified regulatory structure. If s. 29, Article X of the State Constitution is amended or a constitutional amendment related to cannabis or marijuana is adopted, this act shall expire 6 months after the effective date of such amendment.” Section 9, ch. 2017-232, deleted paragraph (2)(a); redesignated paragraphs (2)(b)-(e) as paragraphs (2)(a)-(d); and amended former paragraph (2)(c), now paragraph (2)(b), and subsection (3). If such amendment or adoption takes place, paragraph (2)(a), paragraph (2)(b), renumbered as paragraph (2)(c), and subsection (3), as amended by s. 1, ch. 2017-232, will read:

(a) “Dispensing organization” means an organization approved by the Department of Health under s. 381.986(5) to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices.

(c) “Investigational drug, biological product, or device” means:
1. A drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration; or
2. Medical cannabis that is manufactured and sold by a dispensing organization.

(3) Upon the request of an eligible patient, a manufacturer may, or upon a physician’s order pursuant to s. 381.986, a dispensing organization may:

(a) Make its investigational drug, biological product, or device available under this section.

(b) Provide an investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986 to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986.
499.03  Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—
(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-
forming, toxic, harmful, or new drug subject to s. 499.003(32), or prescription drug as defined in
s. 499.003(40), unless the possession of the drug has been obtained by a valid prescription of a
practitioner licensed by law to prescribe the drug. However, this section does not apply to the
delivery of such drugs to persons included in any of the classes named in this subsection, or to
the agents or employees of such persons, for use in the usual course of their businesses or
practices or in the performance of their official duties, as the case may be; nor does this section
apply to the possession of such drugs by those persons or their agents or employees for such
use:
(a) A licensed pharmacist or any person under the licensed pharmacist’s supervision while
acting within the scope of the licensed pharmacist’s practice;
(b) A licensed practitioner authorized by law to prescribe prescription drugs or any person
under the licensed practitioner’s supervision while acting within the scope of the licensed
practitioner’s practice;
(c) A qualified person who uses prescription drugs for lawful research, teaching, or testing,
and not for resale;
(d) A licensed hospital or other institution that procures such drugs for lawful administration or
dispensing by practitioners;
(e) An officer or employee of a federal, state, or local government; or
(f) A person that holds a valid permit issued by the department pursuant to this part which
authorizes that person to possess prescription drugs.
(2) The possession of a drug under subsection (1) by any person not exempted under this
section, which drug is not properly labeled to indicate that possession is by a valid prescription
of a practitioner licensed by law to prescribe such drug, is prima facie evidence that such
possession is unlawful.
(3) Violation of subsection (1) is a misdemeanor of the second degree, punishable as provided
in s. 775.082 or s. 775.083, except that possession with the intent to sell, dispense, or deliver is
a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
(4) The department may adopt rules regarding persons engaged in lawful teaching, research,
or testing who possess prescription drugs and may issue letters of exemption to facilitate the
lawful possession of prescription drugs under this section.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 5, ch. 84-115; s. 75, ch. 87-243; ss. 30, 52, ch. 92-69; s.
2008-207; s. 42, ch. 2010-161; s. 11, ch. 2016-212.

499.032  Phenylalanine; prescription required.—Phenylalanine restricted formula is declared to
be a prescription drug and may be dispensed only upon the prescription of a practitioner
authorized by law to prescribe prescription drugs.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 31, 52, ch. 92-69; s. 23, ch. 2008-207.

499.033  Ephedrine; prescription required.—Ephedrine is declared to be a prescription drug.
(1) Except as provided in subsection (2), any product that contains any quantity of ephedrine,
a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine
may be dispensed only upon the prescription of a duly licensed practitioner authorized by the
laws of the state to prescribe prescription drugs.
(2) A product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection
(1) if it may lawfully be sold over the counter without a prescription under the federal act; is
labeled and marketed in a manner consistent with the pertinent United States Food and Drug
Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and
distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.

(a) Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:
   1. Theophylline (100-130mg), ephedrine (12.5-24mg).
   2. Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).
   3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).
   4. Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.

(b) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:
   1. Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).
   2. Phenylephrine (not greater than 5mg), ephedrine (not greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).
   (c) Anorectal preparations containing less than 5 percent ephedrine.
   (d) Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.
   (e) Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.

(3) The department may implement this section by rule.

History.—s. 7, ch. 94-309; s. 1, ch. 95-415; s. 61, ch. 2003-1; s. 24, ch. 2008-207.

499.035 Dimethyl sulfoxide (DMSO); labeling and advertising.—
(1) Dimethyl sulfoxide (DMSO) not approved for drug use must be clearly marked in at least 12-point boldfaced type: “May be unsafe. Not approved for human use.”
(2) All advertisements for the sale of dimethyl sulfoxide (DMSO) not approved for drug use must contain, within the advertisement and in bold lettering, the following statement: “Warning. May be unsafe. Not approved for human use.”

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-266; ss. 32, 52, ch. 92-69; ss. 1, 5, 8, ch. 94-309.

499.036 Restrictions on sale of dextromethorphan.—
(1) As used in this section, the term:
   (a) “Finished drug product” means a drug legally marketed under the Federal Food, Drug, and Cosmetic Act that is in finished dosage form. For purposes of this paragraph, the term “drug” has the same meaning as provided in s. 499.003(17).
   (b) “Proof of age” means any document issued by a governmental agency that contains the date of birth and a description or photograph of the person purchasing the finished drug product. The term includes, but is not limited to, a passport, a driver license, or an identification card issued by this state, another state, or any branch of the United States Armed Forces.
   (2)(a) A manufacturer, distributor, or retailer, or its employees and representatives, may not knowingly or willfully sell a finished drug product containing any quantity of dextromethorphan to a person younger than 18 years of age.
(b) A person younger than 18 years of age may not purchase a finished drug product containing any quantity of dextromethorphan.

(3) An employee or representative of a retailer making a retail sale of a finished drug product containing any quantity of dextromethorphan must require and obtain proof of age from the purchaser before completing the sale, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older.

(4)(a) Each sales location of a manufacturer, distributor, or retailer whose employee or representative, during the course of the employee's or representative's employment or association with the manufacturer, distributor, or retailer, sells a finished drug product containing any quantity of dextromethorphan in violation of this section is subject to a written warning for an initial violation and, for each subsequent violation, a civil citation imposing a fine of not more than $100, which shall accrue and may be recovered in a civil action brought by the local jurisdiction. A manufacturer, distributor, or retailer who demonstrates a good faith effort to comply with this section is not subject to citation.

(b) An employee or representative of a manufacturer, distributor, or retailer who, during the course of the employee's or representative's employment or association with the manufacturer, distributor, or retailer, sells a finished drug product containing any quantity of dextromethorphan in violation of this section is subject to a written warning.

(c) A person who possesses or receives a finished drug product containing any quantity of dextromethorphan in violation of this section with the intent to distribute is subject to a civil citation imposing a fine of not more than $100 for each violation, which shall accrue and may be recovered in a civil action brought by the local jurisdiction. A civil citation issued to a person pursuant to this paragraph shall include information regarding how to dispute the citation and shall clearly state that the violation is a noncriminal violation.

(5) A civil citation issued to a manufacturer, distributor, or retailer pursuant to this section shall be provided to the manager on duty at the time the citation is issued. If a manager is not available, a local law enforcement officer shall attempt to contact the manager to issue the citation. If the local law enforcement officer is unsuccessful in contacting the manager, he or she may leave a copy of the citation with an employee 18 years of age or older and mail a copy of the citation by certified mail to the owner's business address, as filed with the Department of State, or he or she may return to issue the citation at a later time. The civil citation shall provide:

(a) The date and approximate time of the sale in violation of this section.

(b) The location of the sale, including the address.

(c) The name of the employee or representative who completed the sale.

(d) Information regarding how to dispute the citation.

(e) Notice that the violation is a noncriminal violation.

(6) To dispute the citation, the recipient of the citation must provide notice of the dispute to the clerk of the county court in the jurisdiction in which the violation occurred within 15 days after receipt of the citation. The local jurisdiction, through its duly authorized officers, shall hold a hearing in the court of competent jurisdiction when a citation for a violation of this section is issued, when the violation is disputed, and when the recipient is issued the citation by a local law enforcement officer employed by or acting on behalf of the jurisdiction. If the court finds in favor of the jurisdiction, the court shall require payment of the fine as provided in this section.

(7) This section shall be applied uniformly throughout the state. Enforcement of this section shall remain with local law enforcement departments and officials charged with the enforcement of the laws of the state.

(8) This section does not:

(a) Impose any restriction on the placement of products in a retail store, direct access of customers to finished drug products, or the maintenance of transaction records.
(b) Apply to a medication containing dextromethorphan that is sold by a retailer pursuant to a valid prescription.

(c) Create a criminal violation. A person who violates this section commits a noncriminal violation as defined in s. 775.08(3).

(9) This section preempts any ordinance regulating the sale, distribution, receipt, or possession of dextromethorphan enacted by a county, municipality, or other political subdivision of the state, and dextromethorphan is not subject to further regulation by such political subdivisions.

History.—s. 1, ch. 2016-176; s. 34, ch. 2017-3.

499.039 Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.—It is unlawful for a person to sell, deliver, or give to a person under the age of 18 years any compound, liquid, or chemical containing toluol, hexane, trichloroethylene, acetone, toluene, ethyl acetate, methyl ethyl ketone, trichloroethane, isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl ether acetate, cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites (butyl nitrite), or any similar substance for the purpose of inducing by breathing, inhaling, or ingesting a condition of intoxication or which is intended to distort or disturb the auditory, visual, or other physical or mental processes.

(1) On the first violation of this section, the department may issue a warning according to s. 499.002(5), if the violation has not caused temporary or permanent physical or mental injury to the user.

(2) If any violation of this section has caused temporary or permanent physical or mental injury to the user, the department may, pursuant to chapter 120, impose fines according to s. 499.066 and may report any violation to the appropriate state attorney for prosecution.

(3) The department shall adopt rules to implement this section.

History.—s. 12, ch. 86-133; s. 1, ch. 89-296; ss. 33, 52, ch. 92-69; s. 239, ch. 99-8; s. 25, ch. 2008-207.

499.04 Fee authority.—The department may collect fees for all drug, device, and cosmetic applications, permits, product registrations, and free-sale certificates. The total amount of fees collected from all permits, applications, product registrations, and free-sale certificates must be adequate to fund the expenses incurred by the department in carrying out this part. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and shall adjust those fees from time to time based on the costs associated with administering this part. The fees are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this part.

History.—s. 34, ch. 82-225; s. 115, ch. 83-218; s. 1, ch. 83-265; ss. 34, 52, ch. 92-69; s. 15, ch. 2000-326; s. 26, ch. 2008-207; s. 13, ch. 2012-143.

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

(a) The fee for a prescription drug manufacturer permit may not be less than $500 or more than $750 annually.

(b) The fee for a device manufacturer permit may not be less than $500 or more than $600 annually.

(c) The fee for a cosmetic manufacturer permit shall be sufficient to cover the costs of administering the cosmetic manufacturer permit program.

(d) The fee for an over-the-counter drug manufacturer permit may not be less than $300 or more than $400 annually.
(e) The fee for a prescription drug repackager permit may not be less than $500 or more than $750 annually.
(f) A manufacturer may not be required to pay more than one fee per establishment to obtain an additional manufacturing permit, but each manufacturer must pay the highest fee applicable to his or her operation in each establishment.
(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.
(a) The fee for a prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.
(b) The fee for an out-of-state prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.
(c) The fee for a nonresident prescription drug manufacturer permit may not be less than $300 or more than $500 annually.
(d) The fee for a retail pharmacy drug wholesale distributor permit may not be less than $35 or more than $50 annually.
(e) The fee for a freight forwarder permit may not be less than $200 or more than $300 annually.
(f) The fee for a veterinary prescription drug wholesale distributor permit may not be less than $300 or more than $500 annually.
(g) The fee for a limited prescription drug veterinary wholesale distributor permit may not be less than $300 or more than $500 annually.
(h) The fee for a third party logistics provider permit may not be less than $200 or more than $300 annually.
(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.
(a) The fee for a veterinary prescription drug retail establishment permit may not be less than $200 or more than $300 annually.
(b) The fee for a health care clinic establishment permit may not be less than $125 or more than $250 annually.
(4) The department shall assess an applicant that is required to have a restricted prescription drug distributor permit an annual fee of not less than $200 or more than $300.
(5) In addition to the fee charged for a permit required by this part, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.
(6) A person that is required to register drugs or devices under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.
(7) The department shall assess an applicant that requests a free-sale certificate a fee of $25. A fee of $2 will be charged for each signature copy of a free-sale certificate that is obtained at the same time the free-sale certificate is issued.
(8) The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.
(9) The department shall assess each person applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record check.
(10) The department shall assess other fees as provided in this part.
499.05 Rules.—
(1) The department shall adopt rules to implement and enforce this chapter with respect to:
   (a) The definition of terms used in this chapter, and used in the rules adopted under this chapter, when the use of the term is not its usual and ordinary meaning.
   (b) Labeling requirements for drugs, devices, and cosmetics.
   (c) The establishment of fees authorized in this chapter.
   (d) The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this chapter.
   (e) The application processes and forms for product registration.
   (f) Procedures for requesting and issuing certificates of free sale.
   (g) Inspections and investigations conducted under s. 499.051 or s. 499.93, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).
   (h) The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this chapter; and a process for the uncontested settlement of alleged violations.
   (i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2. or s. 499.82.
   (j) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.
   (k) Information required from each retail establishment pursuant to s. 499.012(3) or s. 499.83(2)(c), including requirements for prescriptions or orders.
   (l) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) or s. 499.82(14).
   (m) Wholesale distributor reporting requirements of s. 499.0121(14).
   (n) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).
(2) With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.
(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

499.051 Inspections and investigations.—
(1) The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter during business hours for the purpose of enforcing this chapter, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.
(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other
establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or cosmetic.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter and rules adopted under this chapter constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 or s. 499.831 and rules adopted under those sections constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter and the rules adopted by the department to administer this chapter, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5) The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6) The authority to inspect under this section includes the authority to secure:
   (a) Samples or specimens of any drug, device, or cosmetic; or
   (b) Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.

(7)(a) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed.

(b) Information that constitutes a trade secret, as defined in s. 812.081, contained in the complaint or obtained by the department pursuant to the investigation must remain confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution as long as the information is held by the department. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

(c) This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 7, ch. 83-265; s. 5, ch. 86-133; s. 11, ch. 88-159; ss. 37, 52, ch. 92-69; s. 199, ch. 94-218; ss. 5, 8, ch. 94-309; s. 7, ch. 95-366; s. 332, ch. 96-406; s. 240, ch. 99-8; s. 62, ch. 2003-1; s. 21, ch. 2003-155; s. 26, ch. 2007-6; s. 29, ch. 2008-207; s. 8, ch. 2014-89; s. 11, ch. 2016-6; s. 13, ch. 2016-212; s. 4, ch. 2017-51.

499.052 Records of interstate shipment.—For the purpose of enforcing this part, carriers engaged in interstate commerce and persons receiving drugs, devices, or cosmetics in interstate commerce must, upon the request, in the manner set out below, by an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 38, 52, ch. 92-69; s. 30, ch. 2008-207.

499.055 Reports and dissemination of information by department.—

(1) The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under ss. 499.001-499.79, including the nature of any charges and the dispositions of the charges.
(2) The department may also cause to be disseminated such information regarding drugs, devices, and cosmetics as considered necessary in the interest of public health and the protection of consumers against fraud.

(3) This section does not prohibit the department from collecting, reporting, and illustrating the results of its investigations.

(4) The department shall publish on the department’s website and update at least monthly:

(a) A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors against whom the department has initiated enforcement action pursuant to this part to suspend or revoke a permit, seek an injunction, or otherwise file an administrative complaint and the permit number of each such wholesale distributor.

(b) A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors to which the department has issued a permit, including the date on which each permit will expire.

(c) A list of the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 86-133; ss. 39, 52, ch. 92-69; s. 22, ch. 2003-155; s. 31, ch. 2008-207.

499.057 Expenses and salaries.—Except as otherwise provided in the General Appropriations Act, all expenses and salaries shall be paid out of the Professional Regulation Trust Fund.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 40, 52, ch. 92-69; s. 564, ch. 2003-261; s. 14, ch. 2012-143.

499.06 Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.—

(1) When a duly authorized agent of the department finds, or has probable cause to believe, that any drug, device, or cosmetic is in violation of any provision of this part or any rule adopted under this part so as to be dangerous, unwholesome, or fraudulent within the meaning of this part, she or he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order warns all persons not to remove, use, or dispose of such article or processing equipment by sale or otherwise until permission for removal, use, or disposal is given by such agent or the court. It is unlawful for any person to remove, use, or dispose of such detained or embargoed article or processing equipment by sale or otherwise without such permission; and such act is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) When an article or processing equipment detained or embargoed under subsection (1) has been found by such agent to be in violation of law or rule, she or he shall, within 90 days after the issuance of such notice, petition the circuit court, in the jurisdiction of which the article or processing equipment is detained or embargoed, for an order for condemnation of such article or processing equipment. When such agent has found that an article or processing equipment so detained or embargoed is not in violation, she or he shall rescind the stop-sale, stop-use, removal, or hold order.

(3) If the court finds that the detained or embargoed article or processing equipment is in violation, such article or processing equipment shall, after entry of the court order, be destroyed or made sanitary at the expense of the claimant thereof, under the supervision of such agent; and all court costs, fees, and storage and other proper expenses shall be taxed against the claimant of such article or processing equipment or her or his agent. However, when the
violation can be corrected by proper labeling of the article or sanitizing of the processing equipment, and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article be so labeled or processed or such processing equipment be so sanitized, has been executed, the court may by order direct that such article or processing equipment be delivered to the claimant thereof for such labeling, processing, or sanitizing, under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article or processing equipment upon representation to the court by the department that the article or processing equipment is no longer in violation of this part and that the expenses of such supervision have been paid. 

(4) When the department or any of its authorized agents finds in any room, building, vehicle of transportation, or other structure any perishable articles that are unsound or contain any filthy, decomposed, or putrid substances, or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department, or its authorized agent, shall forthwith condemn or destroy such articles or in any other manner render such articles unsalable.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 41, 52, ch. 92-69; s. 592, ch. 97-103; s. 32, ch. 2008-207.

499.062 Seizure and condemnation of drugs, devices, or cosmetics.—
(1) Any article of any drug, device, or cosmetic that is adulterated or misbranded under this part is subject to seizure and condemnation by the department or by its duly authorized agents designated for that purpose in regard to drugs, devices, or cosmetics.

(2) Whenever a duly authorized officer or employee of the department finds cause, or has probable cause to believe that cause exists, for the seizure of any drug, device, or cosmetic, as set out in this part, he or she shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being, subject to seizure under this part and that the article has been detained and seized by the department. Such officer or employee shall also warn all persons not to remove or dispose of the article, by sale or otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) When any article detained or seized under this subsection has been found by the department to be subject to seizure and condemnation, the department shall petition the court for an order of condemnation or sale, as the court directs. The proceeds of the sale of drugs, devices, and cosmetics, less the legal costs and charges, shall be deposited into the Professional Regulation Trust Fund.

(b) If the department finds that any article seized under this subsection was not subject to seizure, the department or the designated officer or employee shall remove the tag or marking.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 42, 43, 44, 52, ch. 92-69; s. 593, ch. 97-103; s. 33, ch. 2008-207; s. 15, ch. 2012-143.

Note.—Subsection (2) intro. former s. 499.063; paragraphs (2)(a), (b) former s. 499.064.

499.065 Inspections; imminent danger.—
(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.
(2) To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Business and Professional Regulation or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3) The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public’s health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

(4) For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

History.—s. 23, ch. 2003-155; s. 6, ch. 2004-328; s. 6, ch. 2006-92; s. 107, ch. 2008-6; s. 34, ch. 2008-207; s. 6, ch. 2012-143.

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this chapter. If it appears that a person has violated any provision of this chapter for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department’s possession.

(2) If any person engaged in any activity covered by this chapter violates any provision of this chapter, any rule adopted under this chapter, or a cease and desist order as provided by this chapter, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter, the rules adopted under this chapter, and the orders of the department authorized by this chapter or to mandate compliance with this chapter, the rules adopted under this chapter, and any order or permit issued by the department under this chapter.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter or rules adopted under this chapter. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this chapter. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;
(b) Any actions taken by the person to correct the violation or to remedy complaints; and
(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which
relate to this chapter, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter.

(5) The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug, device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7) Resignation or termination of an affiliated party does not affect the department’s jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 117, ch. 83-218; s. 1, ch. 83-265; s. 7, ch. 86-133; s. 3, ch. 86-271; ss. 45, 52, ch. 92-69; ss. 4, 5, 8, ch. 94-309; s. 24, ch. 2003-155; s. 35, ch. 2008-207; s. 16, ch. 2012-143; s. 9, ch. 2014-89.

499.0661 Cease and desist orders; removal of certain persons.—

(1) CEASE AND DESIST ORDERS.—

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon a permittee or upon an affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;
2. A violation of a provision of this chapter;
3. A violation of a rule of the department;
4. A violation of an order of the department; or
5. A breach of a written agreement with the department.

(b) The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c) If a hearing is not requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance.

(d) A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party named therein. An uncontested cease and desist order is effective as agreed.

(e) Whenever the department finds that conduct described in paragraph (a) is likely to cause an immediate threat to the public health, it may issue an emergency cease and desist order requiring the permittee or any affiliated party to immediately cease and desist from engaging in the conduct complained of and to take corrective and remedial action. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings under this subsection, the emergency order remains effective until the conclusion of the proceedings under ss. 120.569 and 120.57.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—
(a) The department may issue and serve a complaint stating charges upon an affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:
1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;
2. A willful violation of this chapter; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;
3. A violation of a law involving fraud or moral turpitude which constitutes a felony;
4. A willful violation of a rule of the department;
5. A willful violation of an order of the department; or
6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.
(b) The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.
(c) If a hearing is not requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.
(d) A contested or default order of removal, restriction, or prohibition is effective when reduced to writing and served on the permittee and the affiliated party. An uncontested order of removal, restriction, or prohibition is effective as agreed.
(e)1. The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.
2. Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the permittee and the affiliated party charged. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request a postsuspension hearing to show that continued service to or participation in the affairs of the permittee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.
(f) Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent of the department. Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.
499.067 Denial, suspension, or revocation of permit, certification, or registration.—
(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a
substantial failure to comply with this chapter or chapter 465, chapter 501, or chapter 893, the
rules adopted under those chapters, any final order of the department, or applicable federal
laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.
(b) The department may deny an application for a permit or certification, or suspend or revoke
a permit or certification, if the department finds that:
1. The applicant is not of good moral character or that it would be a danger or not in the best
interest of the public health, safety, and welfare if the applicant were issued a permit or
certification.
2. The applicant has not met the requirements for the permit or certification.
3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in
s. 499.012.
4. The applicant, permittee, or person certified under s. 499.012(15) demonstrates any of the
conditions enumerated in s. 499.012.
5. The applicant, permittee, or person certified under s. 499.012(15) has committed any
violation of this chapter.
(2) The department may deny, suspend, or revoke any registration required by this chapter for
the violation of any provision of this chapter or of any rules adopted under this chapter.
(3) The department may revoke or suspend a permit:
(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the
department;
(b) If the permit was procured, or attempted to be procured, for any other person by making or
causing to be made any false representation; or
(c) If the permittee has violated this chapter or rules adopted under this chapter.
(4) If a permit issued under this chapter is revoked or suspended, the owner, manager,
operator, or proprietor of the establishment shall cease to operate as the permit authorized,
from the effective date of the suspension or revocation until the person is again registered with
the department and possesses the required permit. If a permit is revoked or suspended, the
owner, manager, or proprietor shall remove all signs and symbols that identify the operation as
premises permitted as a drug wholesaling establishment; drug, device, or cosmetic
manufacturing establishment; or retail establishment. The department shall determine the length
of time for which the permit is to be suspended. If a permit is revoked, the person that owns or
operates the establishment may not apply for a permit under this chapter for a period of 1 year
after the date of the revocation. A revocation of a permit may be permanent if the department
considers that to be in the best interest of the public health.
(5) The department may deny, suspend, or revoke a permit issued under this chapter which
authorizes the permittee to purchase prescription drugs if an owner, officer, employee, or other
person who participates in administering or operating the establishment has been found guilty of
a violation of this chapter or chapter 465, chapter 501, or chapter 893, any rules adopted under
those chapters, or any federal or state drug law, regardless of whether the person has been
pardoned, had her or his civil rights restored, or had adjudication withheld.
(6) The department shall deny, suspend, or revoke the permit of a person or establishment if
the assignment, sale, transfer, or lease of an establishment permitted under this chapter will
avoid an administrative penalty, civil action, or criminal prosecution.
(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.833,
as applicable, the department may revoke the permit of the permittee and shall provide notice of
the intended agency action by posting a notice at the department’s headquarters and by mailing
a copy of the notice of intended agency action by certified mail to the most recent mailing
address on record with the department and, if the permittee is not a natural person, to the permittee’s registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 8, ch. 86-133; ss. 12, 14, ch. 88-159; s. 4, ch. 89-296; ss. 46, 52, ch. 92-69; s. 44, ch. 95-144; s. 594, ch. 97-103; s. 17, ch. 2000-326; s. 26, ch. 2003-155; s. 37, ch. 2008-207; s. 20, ch. 2011-141; s. 11, ch. 2014-89; s. 19, ch. 2016-212.

Chapter 499, Part II
ETHER

499.601 Legislative intent; construction.
499.61 Definitions.
499.62 License or permit required of manufacturer, distributor, dealer, or purchaser of ether.
499.63 Forms for applications for licenses and permits.
499.64 Issuance of licenses and permits; prohibitions.
499.65 Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.
499.66 Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.
499.67 Maintenance of records by purchasers; inspections.
499.68 Reports of thefts, illegal use, or illegal possession.
499.69 Possession in or near residential housing prohibited; legal entitlement to possession of premises not a defense.
499.701 Adoption of rules by the department.
499.71 Procedure for cease and desist orders.
499.72 Administrative fines.
499.73 Suspension or revocation of license or permit.
499.74 Conduct of hearings; review of orders of the department.
499.75 Penalties.
499.76 Injunctive relief.
499.77 Exceptions.
499.78 County and municipal ordinances.
499.79 Deposit of fees.

499.601 Legislative intent; construction.—
(1) The Legislature finds that the unregulated possession of bulk quantities of ether poses a substantial risk to the health, safety, and welfare of the citizens of this state, and it is the intent of the Legislature that this part be liberally construed to provide all protection necessary for the citizens of this state.

(2) The provisions of this part are cumulative and shall not be construed as repealing or affecting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of ether as herein provided, in instances in which the provisions of this part may conflict with any other such law, the provisions of this part shall control.
499.61 Definitions.—As used in this part:

1. "Dealer" means any person, firm, corporation, or other entity selling, brokering, or transferring ether to anyone other than a licensed ether manufacturer, distributor, or dealer.
2. "Department" means the Department of Business and Professional Regulation.
3. "Distributor" means any person, firm, corporation, or other entity distributing, selling, marketing, transferring, or otherwise supplying ether to retailers, dealers, or any other entity in the primary channel of trade, but does not include retailers.
4. "Ether" means diethyl ether in any form.
5. "Manufacturer" means any person, firm, corporation, or other entity preparing, deriving, producing, synthesizing, or otherwise making ether in any form or repacking, relabeling, or manipulating ether.
6. "Purchaser" means any person, firm, corporation, or other entity who purchases ether in quantities of 2.5 gallons, or equivalent by weight, or more for any purpose whatsoever, but does not include a dealer, distributor, or manufacturer.

499.62 License or permit required of manufacturer, distributor, dealer, or purchaser of ether.—

1. It shall be unlawful for any person to engage in the business of manufacturing, distributing, or dealing in ether in this state, except when done in conformity with the provisions of this part. No person shall be required to obtain more than one license under this part to handle ether, but each person shall pay the highest fee applicable to her or his operation in each location.
2. Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that a manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether.
3. Any person who manufactures, distributes, or deals in ether at or from more than one location must possess a current valid license for each location.
4. Any person who purchases ether in this state must possess a current valid permit issued by the department, except that no permit shall be required of any person who purchases ether in quantities of less than 2.5 gallons, or equivalent by weight.
5. Annual fees for licenses and permits shall be specified by rule of the department, but shall not exceed the following amounts:
   a. Manufacturer’s license............$700
   b. Distributor’s license.............$700
   c. Dealer’s license..............$350
   d. Purchaser’s permit............$150
6. Licenses and permits issued by the department shall be valid beginning on October 1 of the year for which they are issued and shall expire on the following September 30.
7. A licensed or permitted facility shall renew its license or permit prior to its expiration date. If a renewal application and fee are not filed by the expiration date of any year, the permit may be reinstated only upon payment of a delinquent fee of $50, plus the required renewal fee, within 30 days after the date of expiration. If any person who is subject to the requirements of this part fails to comply with the renewal, the department shall have the authority to seize all ether products and dispose of them as of November 1 of the year the license or permit expires. Any funds collected from the disposal shall be placed in the Professional Regulation Trust Fund.
499.63 Forms for applications for licenses and permits.—

(1) The forms for applications for ether licenses and permits shall be prescribed by the department.

(2) Each application for a license or permit required by the provisions of this part shall be filed in writing with the department. Each application shall require, as a minimum, the full name, date of birth, place of birth, social security number, physical description of the applicant, residence address and telephone number, and business address and telephone number of the applicant. Each application must be accompanied by an accurate and current photograph of the applicant and a complete set of fingerprints of the applicant taken by an authorized law enforcement officer; however, a set of fingerprints shall not be required if the applicant has possessed a valid Florida license or permit under this part during the prior license or permit year and such Florida license or permit has not lapsed or been suspended or revoked. If fingerprints are required, the set of fingerprints shall be submitted by the department to the Department of Law Enforcement for state processing and to the Federal Bureau of Investigation for federal processing. If the application does not require a set of fingerprints, the department shall submit the name and other identifying data to the Department of Law Enforcement for processing. Each application shall be in such form as to provide that the data and other information set forth therein shall be sworn to by the applicant or, if the applicant is a corporation, by all officers of the corporation. The officers applying on behalf of a corporation shall provide all the data and other information required by this subsection and subsection (3), and shall meet all other requirements, which are required of a natural person.

(3) The department may require an applicant to furnish such other information or data not required by this section if the information or data is deemed necessary by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.64 Issuance of licenses and permits; prohibitions.—

(1) Each license and permit issued by the department shall set forth, as a minimum, the full name, date of birth, and physical description of the licensee or permittee and shall have permanently affixed an accurate and current photograph of the licensee or permittee. A license or permit issued to a corporation shall set forth the full name, date of birth, and physical description of the chief executive officer and/or resident agent residing in this state and shall have permanently affixed an accurate and current photograph of the chief executive officer and/or resident agent residing in this state. Each license and permit shall also contain a license or permit number.

(2) The department may, in its discretion, include other data or information in the license or permit when deemed appropriate.

(3) No license or permit shall be issued, renewed, or allowed to remain in effect for any natural person, or for any corporation which has any corporate officer:

(a) Under 18 years of age.
(b) Who has been convicted of a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction, regardless of whether he or she has been pardoned or had his or her civil rights restored.
(c) Who has been convicted of any felony other than a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction and has not been pardoned or had his or her civil rights restored.
(d) Who has been adjudicated mentally incompetent and has not had his or her civil rights restored.

(4) It is unlawful for any person to knowingly withhold information or present to the department any false, fictitious, or misrepresented application, identification, document, information, or data intended or likely to deceive the department for the purpose of obtaining a license or permit.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 597, ch. 97-103.
Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.—

1. It is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether unless she or he is the holder of a current valid license or permit as provided by this part.
2. Whenever the department has reason to believe that any person is or has been violating the provisions of this part or any rules adopted pursuant thereto, the department may, without further process of law, confiscate and dispose of the ether in question. The department is authorized to seize and dispose of any abandoned ether.
3. The department is authorized to enter into contracts with private business entities for the purpose of confiscation and disposal of ether as authorized in subsection (2).
4. The provisions of subsection (1) shall not apply to:
   a. Any common carrier transporting ether into this state or within the boundaries of this state by air, highway, railroad, or water;
   b. Any contract or private carrier transporting ether on highways into this state or within the boundaries of this state by motor vehicle when such contract or private carrier is engaged in such transport pursuant to certificate or permit, by whatever name, issued to them by any federal or state officer, agency, bureau, commission, or department;
   c. Pharmacists, for use in the usual course of their professional practice or in the performance of their official duties;
   d. Medical practitioners, for use in the usual course of their professional practice or in the performance of their official duties;
   e. Persons who procure ether for disposition by or under the supervision of pharmacists or medical practitioners employed by them or for the purpose of lawful research, teaching, or testing, and not for resale;
   f. Hospitals and other institutions which procure ether for lawful administration by practitioners;
   g. Officers or employees of federal, state, or local governments carrying out their official duties; and
   h. Law enforcement agencies of this state or any of its political subdivisions, and the employees thereof, so long as said agencies and employees are acting within the scope of their respective official capacities and in the performance of their duties.
5. The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess ether and may issue letters of exemption to facilitate the lawful possession of ether under this section.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 598, ch. 97-103; s. 39, ch. 98-151.

Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.—

1. It is unlawful for any manufacturer, distributor, or dealer to sell, distribute, or otherwise transfer ether to any person except a person presenting a current valid license or permit as provided by this part.
2. Each sale or transfer of ether shall be evidenced by an invoice, receipt, sales ticket, or sales slip which shall bear the name, address, and license or permit number of the manufacturer, distributor, or dealer and the purchaser or transferee, the date of sale or transfer, and the quantity sold or transferred. All original invoices, receipts, sales tickets, and sales slips shall be retained by the manufacturer, distributor, or dealer, and a copy thereof provided to the purchaser or transferee.
Each manufacturer, distributor, and dealer shall keep an accurate and current written account of all inventories, sales, and transfers of ether. Such records shall be maintained by the manufacturer, distributor, or dealer for a period of 5 years.

Records and inventories as required by subsections (2) and (3) shall be made immediately accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

It is unlawful for any person to knowingly withhold information or to make any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, or sales slip for the sale, distribution, or transfer of ether or upon any account of inventories of ether.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 40, ch. 98-151.

499.67 Maintenance of records by purchasers; inspections.—

(1) It is unlawful for any person to purchase, receive, store, or use ether without maintaining an accurate and current written inventory of all ether purchased, received, stored, and used.

(2) Such records shall include, but not be limited to, invoices, receipts, sales tickets, and sales slips; locations, quantities, and dates of use; the names of any persons using the ether; and the names and license or permit numbers of all persons making such records. Such records shall be maintained by permittees for a period of 5 years.

(3) Such records shall be made accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(4) It is unlawful for any person to knowingly withhold information or make any false or fictitious entry or misrepresentation upon any such records for the purchase, receipt, storage, or use of ether.

(5) It is unlawful for any person to refuse entry or inspection by the department of factories, warehouses, or establishments in which ether is manufactured, processed, repackaged, or held; to refuse entry by the department into any vehicle being used to transport ether; or to refuse the taking of samples by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 41, ch. 98-151.

499.68 Reports of thefts, illegal use, or illegal possession.—

(1) Any sheriff, police department, or law enforcement officer of this state shall give immediate notice to the department of any theft, illegal use, or illegal possession of ether involving any person and shall forward a copy of his or her final written report to the department.

(2) Any licensee or permittee who incurs a loss, an unexplained shortage, or a theft of ether, or who has knowledge of a loss, an unexplained shortage, or a theft of ether, shall, within 12 hours after the discovery thereof, report such loss, theft, or unexplained shortage to the county sheriff or police chief of the jurisdiction in which the loss, theft, or unexplained shortage occurred. Such loss, theft, or unexplained shortage must also be reported to the department by the close of the next business day following the discovery thereof.

(3) Any law enforcement agency which investigates the causes and circumstances of any loss, theft, or unexplained shortage of ether shall forward a copy of its final written report to the department. The department shall retain all such reports in the respective files of the affected licensees and permittees.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 599, ch. 97-103.

499.69 Possession in or near residential housing prohibited; legal entitlement to possession of premises not a defense.—

(1) Notwithstanding the possession of a current valid license or permit as provided in this part, it is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure.
A defendant’s legal entitlement to possession of the property where the violation occurred shall not be a defense to a prosecution for a violation of subsection (1).

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.701 Adoption of rules by the department.—
(1) The department shall adopt and enforce rules necessary to the administration of its authority under this part. The rules must be such as are reasonably necessary for the protection of the health, welfare, and safety of the public and persons manufacturing, distributing, dealing, and possessing ether, and must provide for application forms and procedures, recordkeeping requirements, and security. The rules must be in substantial conformity with generally accepted standards of safety concerning such subject matter.
(2) The department may adopt rules regarding recordkeeping and security for methyl ethyl ketone (MEK) or butyl acetate as needed. These products and records are open to inspection in the same manner as are ether products and records.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 2000-242.

499.71 Procedure for cease and desist orders.—
(1) Whenever the department has reason to believe that any person is or has been violating any provision of this part or any rules adopted pursuant thereto, it shall proceed to determine the matter.
(2) If the department determines that any provision of this part or any rules adopted pursuant thereto have been violated, it shall issue to the person charged with such violation an order requiring such person to cease and desist from such violation or imposing an administrative fine, or both.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.72 Administrative fines.—
(1) If any person violates any provision of this part or any rule adopted pursuant thereto, or violates a cease and desist order issued by the department, the department may impose an administrative fine, not to exceed $5,000 for each violation per day, or may suspend or revoke the license or permit issued to such person, or both. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. The department shall allow the licensee or permittee a reasonable period, not to exceed 30 days, within which to pay to the department the amount of the fine so imposed. If the licensee or permittee fails to pay the fine in its entirety to the department at its office in Tallahassee within the period so allowed, the licenses or permits of such person shall stand revoked upon expiration of such period.
(2) All such fines, monetary penalties, and costs received by the department in connection with this part shall be deposited in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 18, ch. 2012-143.

499.73 Suspension or revocation of license or permit.—
(1) The violation of any provision of this part, any rule adopted pursuant thereto, or any cease and desist order issued by the department by a licensee or permittee as provided in this part shall be cause for revocation or suspension of all licenses or permits held by such licensee or permittee after the department has determined the licensee or permittee to be guilty of such violation.
(2) If the department finds the licensee or permittee to be guilty of such violation, it shall enter its order suspending or revoking the license or permit of the person charged. An order of suspension shall state the period of time of such suspension, which period shall not be in excess of 1 year from the date of such order. An order of revocation may be entered for a period
not exceeding 5 years; such order shall effect the revocation of all licenses or permits then held by the person charged, and during such period no license or permit shall be issued to said person. If, during the period between the beginning of proceedings and the entry of an order of suspension or revocation by the department, a new license or permit has been issued to the person charged, any order of suspension or revocation shall operate effectively with respect to the new license or permit held by such person.

(3) Any person or office of a corporation whose permit or license has been suspended or revoked shall not be issued a new permit or license under any other name or company name until the expiration of the suspension or revocation in which she or he has been involved.

(4) The provisions of this section are cumulative and shall not affect the administrative fine and injunction provisions of ss. 499.72 and 499.76.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 600, ch. 97-103.

499.74 Conduct of hearings; review of orders of the department.—

(1) All hearings shall be conducted in accordance with the provisions of chapter 120.

(2) All review of orders of the department shall be in accordance with the provisions of chapter 120.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.75 Penalties.—

(1) Any person who knowingly manufactures, distributes, or deals in ether without possessing a valid current license as required by s. 499.62(2) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) Any person who knowingly purchases 2.5 gallons, or equivalent by weight, or more of ether without possessing a valid current permit as required by s. 499.62(4) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3) Any person who knowingly withholds information or presents to the department any false, fictitious, or misrepresented application, identification, document, information, statement, or data intended or likely to deceive the department for the purpose of obtaining a license or permit as prohibited by s. 499.64(4) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4) Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether and is not the holder of a valid current license or permit as prohibited by s. 499.65(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) Any person who knowingly sells or otherwise transfers 2.5 gallons, or equivalent by weight, or more of ether to any person who is not the holder of a valid current license or permit as prohibited by s. 499.66(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) Any person who knowingly withholds information or makes any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, sales slip, or account of inventories as prohibited by s. 499.66(5) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(7) Any licensee who knowingly fails to maintain written accounts of inventories or records of sales or transfers as required by s. 499.66(3) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8) Any permittee who knowingly fails to maintain written inventories and records as required by s. 499.67 is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
Any licensee or permittee who fails to report the loss, unexplained shortage, or theft of ether as required by s. 499.68(2) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure as prohibited by s. 499.69(1) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—ss. 10, 11, ch. 86-133; s. 121, ch. 91-224; s. 4, ch. 91-429.

499.76 Injunctive relief.—In addition to the penalties and other enforcement provisions of this part, in the event any person engaged in any of the activities covered by this part violates any provision of this part, any rule adopted pursuant thereto, or any cease and desist order as provided by this part, the department is authorized to resort to proceedings for injunction in the circuit court of the county in which the violation occurred or in which the person resides or has his or her principal place of business and may therein apply for such temporary and permanent orders as the department may deem necessary to restrain such person from engaging in any such activities until such person complies with the provisions of this part, the rules adopted pursuant thereto, and the orders of the department as authorized by this part.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 601, ch. 97-103.

499.77 Exceptions.—Nothing contained in this part shall apply to the regular military and naval forces of the United States, or to the duly organized military forces of any state or territory thereof, provided that they are acting within their respective official capacities and in the performance of their duties.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.78 County and municipal ordinances.—Nothing contained in this part shall affect any existing ordinance, rule, or regulation pertaining to ether in any county or municipality in this state, which ordinance, rule, or regulation is more restrictive than the provisions of this part and the rules adopted pursuant thereto; nor shall the provisions of this part limit the power of any county or municipality to make ordinances, rules, or regulations pertaining to ether which may be more restrictive than the provisions of this part and the rules adopted pursuant thereto.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.79 Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund, and all moneys collected under this part and deposited in the trust fund shall be used by the department in the administration of this part. The Department of Business and Professional Regulation shall maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics program.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 95-144; s. 19, ch. 2012-143.

Chapter 499, Part III
MEDICAL GAS

499.81 Administration and enforcement.
499.82 Definitions.
499.83 Permits.
499.831 Permit application.
499.832 Expiration and renewal of a permit.
499.83 Permitholder changes.
499.84 Minimum qualifications.
499.85 Minimum requirements for the storage and handling of medical gases.
499.86 Security.
499.87 Examination of materials.
499.88 Returned, damaged, and outdated medical gas.
499.89 Due diligence.
499.90 Recordkeeping.
499.91 Policies and procedures.
499.92 Prohibited acts.
499.93 Inspections.
499.931 Trade secret information.
499.94 Fees.

499.81 Administration and enforcement.—
(1) This part is cumulative and shall be construed and applied as being in addition to and not in substitution for or limiting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of medical gas, this part controls over any conflicting provisions.
(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the manufacture and distribution of medical gases.
(3) For the purpose of an investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, subpoena witnesses, and compel the production of books, papers, documents, or other records. Challenges to, and enforcement of, subpoenas and orders shall be handled as provided in s. 120.569.
(4) Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports a violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and prosecuted as required by law.
(5) This part does not require the department to report, for the purpose of instituting proceedings under this part, minor violations of this part when the department believes that the public interest will be adequately served by a written notice or warning.
History.—s. 13, ch. 2014-89.

499.82 Definitions.—As used in this part, the term:
(1) “Adulterated” means a medical gas that:
   (a) Consists, in whole or in part, of impurities or deleterious substances exceeding normal specifications;
   (b) Is produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength and meets the quality and purity characteristics that the medical gas is represented to possess;
   (c) Is held in a container with an interior that is composed in whole or in part of a poisonous or deleterious substance that may render the contents injurious to health; or
   (d) Is represented as having a strength differing from, or quality or purity falling below, the standard set forth in the USP-NF. A medical gas defined in the USP-NF may not be deemed to be adulterated under this paragraph merely because it differs from the standard of strength, quality, or purity set forth in the USP-NF if its difference in strength, quality, or purity from that
standard is plainly stated on its label. The determination as to strength, quality, or purity shall be made:

1. In accordance with the tests or methods of assay in the USP-NF or its validated equivalent; or
2. In the absence or inadequacy of such tests or methods of assay, in accordance with the tests or methods of assay prescribed under the federal act.

(2) “Department” means the Department of Business and Professional Regulation.
(3) “Distribute” or “distribution” means to sell; offer to sell; deliver; offer to deliver; transfer by either the passage of title, physical movement, or both; broker; or give away a medical gas. The term does not include:
(a) The dispensing or administration of a medical gas;
(b) The delivery of, or an offer to deliver, a medical gas by a common carrier in its usual course of business; or
(c) Sales activities taking place in a location owned, controlled, or staffed by persons employed by a person or entity permitted in this state to distribute a medical gas, if that location is not used to physically store or move a medical gas.

(4) “Emergency medical reasons” include:
(a) Transfers between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of a medical gas arising from a long-term delay or interruption of regular distribution schedules.
(b) Sales, purchases, trades, transfers, or use of a medical gas acquired by a medical director or licensed emergency medical services provider for use by the emergency medical services provider and its permitted transport and nontransport vehicles in accordance with the provider’s license under part III of chapter 401.
(c) The provision of emergency supplies of medical gases to nursing homes during the hours of the day when necessary medical gases cannot normally be obtained from the nursing home’s regular distributors.
(d) The transfer of medical gases between retail pharmacies to alleviate a temporary shortage.

(5) “Emergency use oxygen” means oxygen USP administered in emergency situations without a prescription for oxygen deficiency and resuscitation. The container must be labeled in accordance with requirements of the United States Food and Drug Administration.

(7) “Medical gas” means a liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.
(8) “Medical gas-related equipment” means a device used as a component part or accessory used to contain or control the flow, delivery, or pressure during the administration of a medical gas, such as liquid oxygen base and portable units, pressure regulators and flow meters, and oxygen concentrators.
(9) “Misbranded” means having a label that is false or misleading; a label without the name and address of the manufacturer, packer, or distributor and without an accurate statement of the quantities of active ingredients; or a label without an accurate monograph for the medical gas, except in the case of mixtures of designated medical gases where the label identifies the component percentages of each designated medical gas used to make the mixture.
(10) “Medical oxygen” means oxygen USP which must be labeled in compliance with labeling requirements for oxygen under the federal act.
(11) “Product labeling” means the labels and other written, printed, or graphic matter upon an article, or the containers or wrappers that accompany an article, except for letters, numbers, and symbols stamped into the container as required by the federal Department of Transportation.
(12) “USP” means the United States Pharmacopeia.
“Wholesale distribution” means the distribution of medical gas to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas; an offer to sell, purchase, or trade a medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons.

“Wholesale distributor” means any person or entity engaged in wholesale distribution of medical gas within or into this state, including, but not limited to, manufacturers; own-label distributors; private-label distributors; warehouses, including manufacturers’ and distributors’ warehouses; and wholesale medical gas warehouses.

Permits.—

(1) A person or entity that intends to distribute medical gas within or into this state, unless exempted under this part, must obtain the applicable permit before operating as:

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer;

(c) A medical oxygen retail establishment.

(2) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for wholesale distribution, whether within or into this state. A medical gas must remain in the original container obtained by the wholesale distributor and the wholesale distributor may not engage in further manufacturing operations unless it possesses a medical gas manufacturer permit. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a medical gas or distribute a medical gas other than by wholesale distribution unless otherwise authorized under this chapter.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person or entity located in this state which engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid-to-liquid, liquid-to-gas, or gas-to-gas process and distributes those medical gases within this state.

1. A permitted medical gas manufacturer may not manufacture or possess a prescription drug other than a medical gas, unless otherwise authorized under this chapter.

2. A permitted medical gas manufacturer may not distribute a medical gas without obtaining the applicable permit, except that it may engage in wholesale distribution of medical gases that it manufactured without obtaining a medical gas wholesale distributor permit if it complies with this part and the rules adopted under this part that apply to a wholesale distributor.

3. A permitted medical gas manufacturer shall comply with all of the requirements applicable to a wholesale distributor under this part and all appropriate state and federal good manufacturing practices.

(c) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for an entity that is located in the state and that sells or delivers medical oxygen directly to patients in this state. The sale and delivery must be based on a prescription or an order from a practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 does not require a permit as a medical oxygen retail establishment.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a medical gas other than medical oxygen, unless otherwise authorized under this chapter.

2. A medical oxygen retail establishment may fill and deliver medical oxygen to an individual patient based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment must comply with all appropriate state and federal good manufacturing practices. Medical oxygen sold or delivered by a medical oxygen retail
establishment pursuant to an order from a practitioner may not be returned into the retail establishment’s inventory.

3. A medical oxygen retail establishment shall comply with all of the requirements applicable to a wholesale distributor under this part, except for those requirements that pertain solely to nitrous oxide.

(3) An out-of-state wholesale distributor that engages in wholesale distribution into this state must be legally authorized to engage in the wholesale distribution of medical gases as a wholesale distributor in the state in which it resides and provide proof of registration as set forth in s. 499.93(3), if required.

(4) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen for wholesale distributors that also maintain a medical oxygen retail establishment permit.

(5) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

(6) A hospice licensed by the Agency for Health Care Administration pursuant to part IV of chapter 400 is not required to obtain a medical oxygen retail establishment permit to purchase on behalf of and sell medical oxygen to its hospice patients if the hospice contracts for the purchase and delivery of medical oxygen from an establishment permitted pursuant to this part. Sale and delivery to patients by hospices pursuant to this subsection must be based upon a prescription or an order from a practitioner authorized by law to prescribe medical oxygen. For sales to hospices pursuant to this subsection, the medical gas wholesale distributor or the medical gas manufacturer selling medical oxygen to a hospice shall reflect on its invoice the hospice license number provided by the Agency for Health Care Administration and shall maintain such record pursuant to s. 499.89. Both the hospice and the medical oxygen retailer delivering medical oxygen to the patient must maintain a copy of a valid order or prescription for medical oxygen in accordance with s. 499.89 and department rule, which copy must be readily available for inspection.

History.—s. 15, ch. 2014-89; s. 15, ch. 2016-212; s. 35, ch. 2017-3.

499.831 Permit application.—

(1) The department shall adopt rules to establish the form and content of the application to obtain a permit and to renew a permit listed under this part.

(2) An applicant must be at least 18 years of age or be managed, controlled, or overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(3) An application for a permit must be filed with the department and must include all of the following information:

(a) The trade or business name of the applicant, including current and former fictitious names, which may not be identical to a name used by an unrelated entity permitted in this state to dispense or distribute medical gas.

(b) The name or names of the owner and operator of the applicant, if not the same person or entity. The application must also include:

1. If the applicant is an individual, the applicant’s name, business address, and date of birth.

2. If the applicant is a sole proprietorship, the business address of the sole proprietor and the name and federal employer identification number of the business entity.

3. If the applicant is a partnership, the name, business address, date of birth of each partner, the name of the partnership, and the partnership’s federal employer identification number.

4. If the applicant is a limited liability company, the name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized.
5. If the applicant is a corporation, the name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, the federal employer identification number, and, if applicable, the name and business address of the parent company.

(c) A list of disciplinary actions pertinent to wholesale distributors, manufacturers, and retailers of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and any such disciplinary actions against such applicant's principals, owners, directors, or officers.

(d) A complete disclosure of all of the applicant's past felony convictions.

(e) An address and description of each facility and warehouse, including all locations used for medical gas storage or wholesale distribution including a description of each facility's security system.

(4) An applicant shall attest in writing that the information contained in its application is complete and accurate.

(5) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit.

(a) The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(b) The fee for a medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(c) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

(6) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

History.—s. 16, ch. 2014-89.

499.832 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. Upon approval of a renewal application by the department and payment of the required renewal fee, the department shall renew a permit issued under this part pursuant to the rules adopted under this part.

(3) A renewal application may be accepted up to 60 days after the expiration date of the permit if, along with the permit renewal fee, the applicant submits an additional renewal delinquent fee of $100. A permit that expired more than 60 days before a renewal application was submitted or postmarked may not be renewed.

(4) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person, entity, or establishment holding the permit must cease all permit-related activities. In order to engage in such activities, the person, entity, or establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before engaging in an activity that requires a permit under this part.

(5) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

History.—s. 17, ch. 2014-89.

499.833 Permitholder changes.—

(1) A permit issued under this part is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily.
(2) A permit issued under this part is not valid for an establishment other than the establishment for which it was originally issued.

(3) The department may approve the following permit changes:
(a) Change of location.—A person or entity permitted under this part must notify and receive approval from the department before changing location. The department shall set a change-of-location fee not to exceed $100.
(b) Change in ownership.—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. Such application must be submitted and approved by the department before the change of ownership takes place. However, if a permitted wholesale distributor or manufacturer is changing ownership and the new owner has held another permit that allows the wholesale distribution of medical gas under this chapter for the preceding 18 months without having been found in violation of the provisions of this chapter relating to medical gases, then the new owner may operate under the permit of the acquired entity if the new owner submits the application for a new permit by the first business day after ownership is transferred or assigned. A new owner operating under the original permit is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.
(c) Change of name.—A permitholder may make a change of business name without submitting a new permit application. However, the permitholder must notify the department before making the name change.
(d) Closure.—If an establishment permitted under this part closes, the owner must notify the department, in writing, before the effective date of the closure and must:
1. Return the permit to the department; and
2. Indicate the disposition of any medical gas authorized to be distributed or dispensed under the permit, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.
(e) Change in information.—Any change in the information required under this part, other than the changes in paragraphs (a)-(d), shall be submitted to the department within 30 days after such change occurs.
(4) A permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, meeting the applicable permitting requirements for the new permit type, and paying any difference between the permit fees. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit. The new permit retains the expiration date of the original permit.

History.—s. 18, ch. 2014-89.

499.834 Minimum qualifications.—The department shall consider all of the following factors in determining eligibility for, and renewal of, a permit for a person or entity under this part:
(1) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to prescription drugs.
(2) Felony convictions of the applicant under a federal, state, or local law.
(3) The applicant’s past experience in the manufacture, retail, or distribution of medical gases.
(4) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing, retailing, or distribution of prescription drugs.
(5) Any suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding prescription drugs.
(6) Compliance with previously granted licenses or permits.
(7) Compliance with the requirements that distributors or retailers of medical gases maintain records and make records available to the department licensing authority or federal, state, or local law enforcement officials.
(8) Other factors or qualifications the department has established in rule that are relevant to and consistent with the public health and safety.

History.—s. 19, ch. 2014-89.

499.84 Minimum requirements for the storage and handling of medical gases.—
(1) A facility where a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported, to avoid any negative effect on the identity, strength, quality, or purity of the medical gas, must:
(a) Be of suitable construction to ensure that medical gases are maintained in accordance with the product labeling of the medical gas or in compliance with the USP-NF;
(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper permitted operations;
(c) Have adequate storage areas with appropriate lighting, ventilation, space, equipment, and security conditions;
(d) Have a quarantined area for storage of medical gases that are suspected of being misbranded, adulterated, or otherwise unfit for distribution;
(e) Be maintained in an orderly condition;
(f) Be located in a commercial location and not in a personal dwelling or residence location, except for a personal dwelling location used for on-call delivery of oxygen USP for home care use if the person providing on-call delivery is employed by or acting under a written contract with an entity that holds a medical oxygen retailer permit;
(g) Provide for the secure and confidential storage of patient information, if applicable, with restricted access and policies and procedures to protect the integrity and confidentiality of patient information; and
(h) Provide and maintain appropriate inventory controls to detect and document any theft of nitrous oxide.
(2) Medical gas shall be stored under appropriate conditions in accordance with the manufacturer’s recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards.
(3) Medical gas shall be packaged in accordance with official compendium standards, such as the USP-NF.

History.—s. 20, ch. 2014-89; s. 63, ch. 2015-2.

499.85 Security.—
(1) A permitholder that has a facility used for the distribution or retailing of medical gases shall protect such gases from unauthorized access by implementing all of the following security measures:
(a) Keeping access from outside the premises well controlled and to a minimum.
(b) Ensuring the outside perimeter of the premises is well lit.
(c) Limiting access into areas where medical gases are held to authorized personnel.
(d) Equipping all facilities with a fence or other system to detect or deter entry after hours.
(2) A facility used for distributing or retailing medical gases shall be equipped with a system that provides suitable protection against theft, including, if appropriate, protection against theft of
computers or electronic records and the protection of the integrity and confidentiality of data and
documents.
(3) A facility used for wholesale distribution of medical gases shall be equipped with inventory
management and control systems that protect against, detect, and document any instances of
theft of nitrous oxide.
(4) If a wholesale distributor uses electronic distribution records, the wholesale distributor shall
employ, train, and document the training of personnel in the proper use of such technology and
equipment.
(5) Vehicles used for on-call delivery of oxygen USP and oxygen-related equipment for home
care use by home care providers may be parked at a place of residence and must be locked
and equipped with an audible alarm when not attended.
(6) The department shall adopt rules that govern the distribution of medical oxygen for
emergency use by persons authorized to receive emergency use oxygen. Unless the laws of
this state specifically direct otherwise, such rules must be consistent with federal regulations,
including the labeling requirements of oxygen under the federal act. Such rules may not be
inconsistent with part III of chapter 401 or rules adopted thereunder.
History.—s. 21, ch. 2014-89.

499.86 Examination of materials.—
(1) A wholesale distributor must visually examine a medical gas container upon receipt from
the manufacturer in order to identify the medical gas stored within and to determine if the
container has been damaged or is otherwise unfit for distribution. Such examination must occur
in a manner that would reveal damage to the container which could suggest possible
adulteration or misbranding.
(2) A medical gas container that is found to be damaged or otherwise unfit pursuant to
subsection (1) must be quarantined from the stock of medical gas until a determination is made
that the medical gas in question is not misbranded or adulterated.
(3) An outgoing shipment must be inspected to identify the medical gases in the shipment to
ensure that medical gas containers that have been damaged in storage or held under improper
conditions are not distributed or dispensed.
(4) A wholesale distributor must review records documenting the acquisition of medical gas
upon receipt for accuracy and completeness.
History.—s. 22, ch. 2014-89.

499.87 Returned, damaged, and outdated medical gas.—
(1) A medical gas that has left the control of the wholesale distributor may be returned to the
wholesale distributor or manufacturer from which it was acquired, but may not be resold as a
medical gas unless it is reprocessed by a manufacturer using proper and adequate controls to
ensure the identity, strength, quality, and purity of the reprocessed medical gas.
(2) A medical gas that has been subjected to improper conditions, such as a fire, accident, or
natural disaster, may not be salvaged or reprocessed.
(3) A medical gas, including its container, which is damaged, misbranded, or adulterated must
be quarantined from other medical gases until it is destroyed or returned to the manufacturer or
wholesale distributor from which it was acquired. External contamination of a medical gas
container or closure system which does not impact the integrity of the medical gas is not
considered damaged or adulterated for purposes of this subsection. If a medical gas is
adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be
provided to the manufacturer or wholesale distributor from which the medical gas was acquired
and to the appropriate boards and federal regulatory bodies.
(4) A medical gas container that has been opened or used but is not adulterated or
misbranded is considered empty and must be quarantined from nonempty medical gas
containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(5) A medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

History.—s. 23, ch. 2014-89.

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the United States Food and Drug Administration;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is legally authorized to distribute medical gas within or into the state;

(c) The name of the responsible facility contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer’s or wholesale distributor’s policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer, as required under subsection (1), if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration; and

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required by s. 499.89(1), as applicable.

History.—s. 24, ch. 2014-89.

499.89 Recordkeeping.—

(1) A permitholder under this part shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases, as applicable. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. ss. 211.196 and 820.160(b). Such records must include all of the following information, which may be kept in two separate documents, one related to the distribution of medical gas and the other related to the receipt of medical gas:

(a) The dates of receipt and distribution or other disposition of the medical gas.

(b) The name, address, and license or permit number and its expiration date for the person or entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, and license or permit number and its expiration date for the person or entity receiving the medical gas, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received, distributed, or dispensed.

(2) Such records shall be made available for inspection and copying by an authorized official of any federal, state, or local governmental agency for a period of:

(a) Three years following the distribution date of high pressure medical gases.

(b) Two years following the distribution date for cryogenic or refrigerated liquid medical gases.

(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention
period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) A wholesale distributor shall maintain records sufficient to aid in the mandatory reporting of any theft, suspected theft, or other significant loss of nitrous oxide to the department and other appropriate law enforcement agencies.

History.—s. 25, ch. 2014-89; s. 16, ch. 2016-212.

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and distribution of medical gases and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures all of the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:
   (a) Action initiated at the request of the United States Food and Drug Administration or any federal, state, or local law enforcement or other government agency, including the department; or
   (b) Voluntary action by a manufacturer of medical gases to remove defective or potentially defective medical gases from the market.
(2) A procedure that includes preparation for, protection against, and responding to a crisis that affects the security or operation of a facility that stores medical gases in the event of a strike; a fire, flood, or other natural disaster; or other local, state, or national emergency.
(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

History.—s. 26, ch. 2014-89.

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of a medical gas that is adulterated, misbranded, or is otherwise unfit for distribution.
(2) The adulteration or misbranding of a medical gas.
(3) The receipt of a medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit, and the delivery or proffered delivery of such medical gas for pay or otherwise.
(4) The alteration, mutilation, destruction, obliteration, or removal of all or any part of the product labeling of a medical gas, or the willful commission of any other act with respect to a medical gas that results in its being misbranded.
(5) The purchase or receipt of a medical gas from a person not authorized to distribute or dispense medical gas or who is not exempted from permitting requirements to wholesale distribute medical gas to such purchaser or recipient.
(6) The knowing and willful sale or transfer of a medical gas to a recipient who is not legally authorized to receive a medical gas, except that a violation does not exist if a permitted wholesale distributor provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with the notice of location change requirements of s. 499.833(3)(a), provided that the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.
(7) The failure to maintain or provide records required under this part and the rules adopted under this part.
(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part or the rules adopted under this part.

(9) The distribution of a medical gas that was:
   (a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;
   (b) Donated or supplied at a reduced price to a charitable organization; or
   (c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a license or permit or operating without a valid license or permit, if one is required.

(11) The obtaining of, or attempt to obtain, a medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a medical gas.

(12) Except for emergency use oxygen, the distribution of a medical gas to a patient without a prescription from a practitioner authorized by law to prescribe a medical gas.

(13) The distribution or dispensing of a medical gas that was previously dispensed by a pharmacy or a practitioner authorized by law to prescribe.

(14) The distribution or dispensing of a medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of the medical gas.

(15) Failure to report an act prohibited under this part or the rules adopted under this part.

(16) Failure to exercise due diligence as provided in s. 499.88.

History.—s. 27, ch. 2014-89; s. 64, ch. 2015-2.

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:
   (a) Adulterates or misbrands a medical gas with intent to defraud or deceive;
   (b) Knowingly purchases or receives a medical gas from a person not legally authorized to distribute or dispense medical gas;
   (c) Knowingly engages in the wholesale distribution of, or sells, barters, brokers, or transfers, a medical gas to a person not legally authorized to purchase or receive medical gas in the jurisdiction in which the person receives the medical gas. A permitted wholesale distributor that provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with only the change of location notice requirement under s. 499.833(3)(a) does not commit a violation of this paragraph if the wholesale distributor notifies the department of the transaction no later than the next business day; or
   (d) Knowingly falsely creates a label for a medical gas or knowingly misrepresents a factual matter contained in a label for a medical gas.

(2) A person found guilty of an offense under this section, under the authority of the court convicting and sentencing the person, shall be ordered to forfeit to the state any real or personal property:
   (a) Used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and
   (b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized by law, and held until the case against a defendant is adjudicated. Moneys ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the department and other agencies involved in the investigation and prosecution that led to the
conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution that led to the conviction.

History.—s. 28, ch. 2014-89; s. 65, ch. 2015-2.

499.93 Inspections.—
(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department, including inspections for initial permitting, permit renewal, and a permitholder's change of location. The department may recognize a third party to inspect wholesale distributors in this state or other states pursuant to a schedule to be determined by the department.

(2) The department may recognize another state's inspections of a manufacturer or wholesale distributor located in that state if such state's laws are deemed to be substantially equivalent to the laws of this state by the department.

(3) A manufacturing facility of medical gases is exempt from routine inspection by the department if:
   (a) The manufacturing facility is currently registered with the United States Food and Drug Administration under s. 510 of the federal act and can provide proof of registration, such as a copy of the Internet verification page; and
   (b) The manufacturing facility can provide proof of inspection by the Food and Drug Administration, or if the facility is located in another state, inspection by the Food and Drug Administration or other governmental entity charged with regulation of good manufacturing practices related to medical gases in that state within the past 3 years, which demonstrates substantial compliance with current good manufacturing practices applicable to medical gases.

(4) A permitholder under this part shall exhibit or have readily available its state permits and its most recent inspection report administered by the department.

History.—s. 29, ch. 2014-89.

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081 and designated as a trade secret by an applicant or permitholder must be maintained as required under s. 499.051. This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

History.—s. 30, ch. 2014-89; s. 12, ch. 2016-6.

499.94 Fees.—A fee collected for a permit under this part shall be deposited into the Professional Regulation Trust Fund. Moneys collected under this part shall be used for administering this part. The department shall maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program.

History.—s. 31, ch. 2014-89.
Chapter 61N-1
REGULATIONS FOR DRUGS, DEVICES AND COSMETICS

61N-1.001 General Regulations; Definitions
(1) A word or phrase defined in the federal Food, Drug, and Cosmetic Act as defined in paragraph 499.002(1)(b), F.S., shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S., or Rule Chapter 61N-1, F.A.C.

(2) In addition to definitions contained in Sections 499.003, 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S., and to Rule Chapters 61N-1 and 61N-2, F.A.C.:
   (a) “Administer” or “administration” – means the direct application or introduction of a single dose of drugs by a legally authorized person to or into the body of an individual human or animal patient whether by injection, inhalation, ingestion or any other means.
   (b) “Authorized absence” – means, for purposes of Section 499.012(16)(d)3., F.S., the physical absence of the designated representative from the permitted establishment, for a cumulative 60 calendar days in any 365 calendar day period for situations such as: the birth of the employee’s child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the care of a family member (child, spouse, or parent) with a health condition, where the employee is needed to care for the family member; or the employee’s own serious health condition makes the employee unable to perform the functions of the designated representative.
   (c) “Authorized recipient” – means a person permitted by or otherwise authorized by Florida law, or by the law of the jurisdiction in which the person receives the prescription drugs, to purchase, own, receive or possess those
prescription drugs. The term includes:
1. Any pharmacy licensed pursuant to Chapter 465, F.S., except a Class I Institutional Pharmacy since it is only authorized to possess dispensed prescription drugs and medical oxygen for administration to its patients,
2. Any person who is authorized by the law where the delivery occurs to purchase, own, receive or possess prescription drugs, or
3. A licensed ship captain, first officer, or designated medical officer for a vessel engaged in international trade or in trade between ports of the United States or for any merchant vessel belonging to the U.S. Government. The prescription drugs must be intended solely for emergency medical purposes and the wholesale distributor must deliver the prescription drugs directly to the ship or transfer possession to the appropriate ship’s officer as near to the ship as permitted by state and federal law.
(d) “Broker” – means a person participating in the wholesale distribution of a prescription drug by buying, purchasing, or otherwise taking ownership of or title to the prescription drug and selling or transferring, or offering to sell or transfer, ownership of or title to the prescription drug to a person other than the patient or the patient’s agent without taking physical possession of the prescription drug.
(e) “Change in Ownership” – means that there has been a transfer or assignment of a majority of the direct ownership or controlling interest of a permitted establishment or that a lessee of a permitted establishment agrees to or becomes legally liable for the operation of the establishment. A transfer or assignment of a majority of direct ownership or controlling interest of a permitted establishment occurs where an event or other transaction occurs and the result of such event or transaction is that more than 50% of the ownership interest or controlling interest of the permitted establishment resides with a person who prior to the event or transaction did not own or control more than a 50% ownership interest in the permitted establishment. A change in the permitted establishment’s federal identification number or the taxpayer identification number is indicative of a change in ownership, but is not dispositive; a change of ownership could occur where the federal identification number or the taxpayer identification number does not change. For a publicly traded corporation, the changing of officers or directors is not a change in ownership nor is the change in ownership of a parent company provided that such change does not result in more than a 50% change in the ownership or controlling interest of any permitted establishment.
(f) “Chief Executive Officer” – means the owner or the highest ranking official of a corporation, company, or business.
(g) “Electronic signature” – means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.
(h) “Established safe and effective indication” – means any indication that has been approved as safe and effective by the FDA, which is generally recognized as safe and effective under conditions established by the FDA, or which is otherwise in compliance with FDA’s regulations.
(i) “FDA” – means the United States Food and Drug Administration.
(j) “Intracompany transfer” – means, pursuant to Section 499.003(34), F.S., a distribution of a specific unit of a prescription drug between two establishments wholly owned and operated by the same business entity.
(k) “Legend Device or Restricted Device” – means any device which can be dispensed only by the prescription or order of a licensed practitioner and which device on its label bears either the words: “Caution: Federal Law restricts this device to sale by or on the order of a ________,” the blank to be filled with the word “physician,” “dentist,” “veterinarian,” or with the descriptive designation of any practitioner licensed by law to use or prescribe the device; “Caution: Federal Law prohibits dispensing without prescription; “Rx Only;” or “Caution: Florida Law prohibits dispensing without prescription.”
(l) “Minimal quantities” for the purpose of distribution of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with Chapter 465, F.S., pursuant to Section 499.003(48)(m), F.S., means the total annual dollar volume of prescription drugs sold does not exceed five percent of the total dollar volume of that pharmacy’s annual prescription drug sales.
(m) “Point of origin” – means the location from which the manufacturer transfers title, and the location from which the manufacturer transfers possession, if different, of the specific unit of the prescription drug being transferred or sold.
(n) “Practitioner” means a person who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes.

(o) “Principal address” or “principal business address” means the person’s primary place of business.

(p) “Product” – anything produced or made either naturally or artificially.

(q) “Propagation” of a drug – means, as used under the definition of “manufacture” at Section 499.003(29), F.S., for purposes of permitting under Section 499.012, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer’s affiliated group or is a contract distribution site.

(r) “Provides prescription services to the public” – means, for the purposes of the retail pharmacy wholesaler permit, holding the pharmacy out to the public through prominently displayed pharmacy signs on the exterior of the building and adequate inventory on hand to fill a variety of prescriptions for a variety of medical conditions that would be required by the public generally.

(s) “Readily available” and “readily retrievable” mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request (unless the permitted address is not within the state in which case a 48 hour timeframe is available for producing records). Required records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

(t) “Regular and systematic supplying of a drug” for the purpose of distributions of prescription drugs between licensed pharmacies operating in end-stage renal dialysis clinics pursuant to Section 499.01(2)(h)5., F.S., means the distribution of that prescription drug where the receiving pharmacy:
1. Has failed to establish a written policy and procedure for forecasting the pharmacy’s prescription drug inventory needs based on the pharmacy’s historical prescription drug dispensing records,
2. Has failed to establish and maintain an inventory of prescription drugs based on historical prescription drug dispensing records; and,
3. Has implemented a business practice where a prescription drug shortage is resolved primarily by obtaining prescription drugs from another pharmacy under common ownership.

(u) “Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution” means:
1. Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 to bottles of 100.
2. Altering a manufacturer’s package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.
3. Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:
   a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
   b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

(v) “Rx” – means prescription.

(w) “Sale” – includes any transfer of title or ownership whether by barter, exchange or gift.

(x) “Separate and distinct cosmetic product” – means a cosmetic product for that establishment which is, or will be sold, distributed, or given away. The adding of color, flavor, or scents does not make a separate and distinct
cosmetic product for each variation.  
(y) “Separate and distinct device product” – means a device product in its finished form for that manufacturer which is, or will be sold, distributed, or given away. The function or use of the device determines whether a device is separate and distinct. 
(z) “Separate and distinct drug product” – means a drug product in the finished form and strength for that manufacturer which is, or will be sold, distributed or given away. 
(aa) “Specific unit of a prescription drug” – means the individual saleable unit of a specific prescription drug being transferred or sold, which is capable of being serialized to contain its own serial number, which drug is identified by name, strength, dosage form, container size, and lot number. 
(bb) “State Current Good Manufacturing Practices” means current good manufacturing practices and quality system regulations as prescribed as of 6/1/2015 in Title 21 Code of Federal Regulations, Parts 210, 211, 212, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, https://www.flrules.org/Gateway/reference.asp?No=Ref-06161, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the requirements for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C. 
(cc) “Unapproved new drug” – means any drug which has not been approved or otherwise authorized for use under the federal act, 21 U.S.C. ss. 301 et seq., and the regulations promulgated thereunder or which does not have a Notice of Claimed Investigational Exemption on file with the United States Food and Drug Administration. 
(dd) “Usual course of business as carriers” – means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes: 
1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR s. 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and, 
2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 61N-1.012(1), (2), F.A.C., apply to all distributions of prescription drugs under this sub-sub paragraph. In all such distributions to commercial airlines, the recipient’s license number shall be the registration number assigned to the carrier by the Federal Aviation Administration. 
(ee) “Valid client-veterinarian relationship” – means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. 
(ff) “Verifiable account” – means a number issued by the manufacturer to a wholesaler when the wholesaler sets up an account with the manufacturer for the purchase of a prescription drug from that manufacturer that uniquely identifies the wholesaler and that is to be used on a recurring basis. 
(gg) “Wholesaler” – means a person who engages in the wholesale distribution of a prescription drug.

Rulemaking Authority 499.003(48)(m), 499.024, 499.025(5), 499.01(2), (3), (4), 499.0121(6), 499.012(5), 499.012(12), 499.025, 499.03(4), 499.05 FS. Law Implemented 499.003, 499.005, 499.0054, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History–New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06, 12-27-07, Formerly 64F-12.001, Amended 12-7-15, 10-10-16.
61N-1.006 Drugs and Devices; Labeling Requirements.

(1) The department adopts and incorporates by reference the labeling requirements for prescription drugs and over-the-counter drugs as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 1-1299 (as of 10/1/03).

(a) The label on the immediate container of each unit dose repackaged drug product or multiple unit prepackaged drug product must contain the following:

1. Brand or generic name, or both;
2. Strength of drug;
3. Dosage form;
4. Manufacturer’s name and lot number or a control number if a log is maintained which cross references the control number with the manufacturer’s name and lot number; and
5. Expiration date.

(b) An authorized practitioner dispensing complimentary prescription drugs to his own patients may dispense them in the manufacturer’s package which shall also include the practitioner’s name, the patient’s name and the date dispensed. If complimentary prescription drugs are not dispensed in the manufacturer’s labeled package, they shall be dispensed in a container which bears a label containing the following:

1. Practitioner’s name and address;
2. Patient’s name;
3. Date dispensed;
4. Name and strength of drug;
5. Directions for use; and
6. Expiration date.

(c) A Veterinary Legend Drug Retail establishment shall attach a label to the original, sealed manufacturer’s container in a manner which leaves the manufacturer’s labeling intact and legible, upon the sale of a veterinary legend drug to a consumer. The label shall bear the following:

1. Name, address and veterinary legend drug retail establishment number;
2. Prescribing veterinarian’s name;
3. Name of the animal or kennel name if so authorized;
4. Date prescription filled or refilled;
5. Prescription number or other prescription identification adequate to readily identify the prescription; and
6. Directions for use.

(2) The department adopts and incorporates by reference the labeling requirements for medical devices as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 800-895 (as of 10/1/03).

Rulemaking Authority 499.05, 499.0122 FS. Law Implemented 499.007, 499.0122, 499.013 FS. History–New 1-1-77, Amended 12-12-82, 7-8-84, Formerly 10D-45.39, Amended 11-26-86, 7-1-96, Formerly 10D-45.039, Amended 1-26-99, 4-17-01, 1-1-04, Formerly 64F-12.006.

61N-1.007 Compressed Medical Gases.

(1) Each compressed medical gases manufacturer or medical oxygen retailer who manufactures or refills compressed medical gases must comply with the current good manufacturing practice regulations for drug products promulgated by the FDA in 21 C.F.R. Parts 200-299 and the “Compressed Medical Gases Guideline” issued by the Center for Drug Evaluation and Research, FDA in February 1989, which are incorporated by reference herein. Deviations from these requirements authorized in writing by the FDA will be recognized by the department when determining compliance with current good manufacturing practices for compressed medical gases.

(2) Each compressed medical gases manufacturer or medical oxygen retailer that refills tanks must establish and follow detailed written procedures covering: production and process controls; training; prefill, fill and post-fill operations; analytical testing; labeling procedures; calibration and maintenance of equipment; distribution; testing and approval or rejection of drug product containers and closures; recall procedures; recordkeeping; and complaint
Labels and Labeling. In those instances where the FDA has not promulgated a final regulation related to labeling of a compressed medical gas, the label must include the general requirements of: name and address of the manufacturer or distributor; established name of the gas; contents in terms of the volume of gas in liters or cubic feet at specified temperature and 1 atmosphere of pressure; lot number; statement of ingredients (for mixtures); directions for use statement; applicable warning statements; and the prescription statement. Although oxygen intended to treat a medical condition is regarded as a prescription drug, the FDA has not objected to emergency use oxygen being marketed without a prescription. If Oxygen U.S.P. is sold for emergency use, then the label is required to contain the statement: “For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, prescription statement”. The prescription statement is “Rx Only” or the prescription symbol followed by the word “Only.” All prescription medical oxygen must also include the following:

(a) If the container is disposable, the label must bear the statement “Disposable Container. Federal Law Prohibits Refilling. Do Not Puncture or Discard Container into Fire or Incinerator.”

(b) If the container is non-disposable and may be refilled, the label must bear the statement “Federal Law Requires that this Container be Refilled with Oxygen U.S.P. Only by Establishments Registered as a Drug Producer in accordance with the Federal Food, Drug, and Cosmetic Act.”

(c) A statement whether the oxygen was produced by the air-liquefaction process;

(d) The warning statement shall be: “Warning – uninterrupted use of high concentrations of oxygen for more than five hours may be harmful. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment. Keep Out of Reach of Children. Contents under high pressure and can vigorously accelerate combustion. Keep free from oil and grease. Do not use or store near heat or open flame and use only with equipment conditioned for oxygen service.”

Rulemaking Authority 499.05, 499.012(2)(b) FS. Law Implemented 499.006, 499.007, 499.012, 499.0122, 499.013 FS. History–New 7-1-96, Formerly 10D-45.0442, Amended 1-26-99, 1-1-04, Formerly 64F-12.007.

61N-1.008 Complimentary Human Prescription Drug Samples: Distribution and Disposal.

(1) Charitable Donations of Prescription Drug Samples. A physician or other authorized recipient of prescription drug samples may donate samples received according to Section 499.028, F.S., to a Restricted Prescription (Rx) Drug Distributors – Charitable Organization permittee; to a charitable institution in this state for administration or dispensing by the charitable institution provided the charitable institution is otherwise licensed to administer or dispense prescription drugs; or to a charitable organization outside of this state that is licensed by that state, if so required. The donation and transfer, however, must be made in accordance with these provisions and the laws or regulations of other applicable jurisdictions.

(a) The donation must be freely given and not encumbered by any expressed or implied requirement or expectation of reimbursement or payment of any kind so as not to constitute a sale, purchase, or trade.

(b) A donated sample must be suitable for use, i.e., not misbranded or adulterated and must be in its original, unopened package with its labeling intact.

(c) A complete and accurate donation record must be prepared and maintained by the donor and recipient. The donation record shall include the elements set forth in subsection 61N-1.012(15), F.A.C.:

(d) The recipient charitable organization shall provide the donor with a written certification that the recipient charitable organization is in conformity with all requirements of the state and federal regulations affecting receipt of prescription drug samples.

(2) Disposal. All complimentary or sample packages of prescription drugs which are expired shall be returned to the manufacturer or distributor. Complimentary or sample packages of prescription drugs which are otherwise unsuitable for the purpose of administering or dispensing may be returned to the manufacturer or distributor or may be destroyed in accordance with the provisions of subsection (4). Prescription drug samples may be sent to a reverse distributor if the manufacturer of the sample has authorized the reverse distributor to handle that manufacturer’s prescription drug sample returns.
(3) Complimentary or sample packages of prescription drugs returned to the manufacturer or distributor from which obtained or to a reverse distributor acting on behalf of the manufacturer, must be documented with records which include the date of the return; the name, form and quantity of the substance by lot number; the name, address, and license or permit number, of the person making the return; and the name, address, and license or permit number, of the manufacturer or person to whom the prescription drug samples are returned.

(4) The destruction of complimentary or sample packages of prescription drugs which may be destroyed must be documented with a complete inventory identifying the items destroyed and a notation on the inventory as to the date and method of destruction.

Rulemaking Authority 499.01, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.05 FS. Law Implemented 499.014, 499.028, Part I, Ch. 499 FS. History—New 12-12-82, Amended 7-8-84, Formerly 10D-45.445, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.0445, Amended 1-26-99, 4-17-01, Formerly 64F-12.008.

61N-1.009 Cosmetic Labeling Requirements.
The department adopts and incorporates by reference the labeling requirements for cosmetics as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 700-799 (as of 10/1/03).

Rulemaking Authority 499.013, 499.05 FS. Law Implemented 499.009, 499.013 FS. History—New 1-1-77, Amended 12-12-82, Formerly 10D-45.48, Amended 7-1-96, Formerly 10D-45.048, Amended 1-26-99, 4-17-01, 1-1-04, Formerly 64F-12.009.

61N-1.010 Requirements for Manufacturing Cosmetics.
(1) All persons who manufacture or relabel cosmetics in Florida must follow the minimum requirements for manufacturing contained in this section to help assure product safety and quality. If a person does not engage in all phases of cosmetic manufacturing, that person need only comply with paragraphs applicable to those operations in which the person is engaged.

(a) As used in this section, “good manufacturing practice” means that part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures.

(b) As used in this paragraph, “internal audit” means a systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these rules and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

(c) As used in this paragraph, “standard operating procedure” means instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives.

(2) Buildings and facilities requirements.
Buildings and facilities used for manufacture, processing, packaging, or relabeling of cosmetics must:

(a) Be constructed and maintained in a clean and orderly manner to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (this applies to containers, closures, labels and labeling materials as well);

(b) Be free of filth and infestation by rodents, birds, insects, and other vermin;

(c) Have a designated quarantine area for the storage of products that are suspected of being contaminated, adulterated, or otherwise potentially injurious to users;

(d) Have floors, walls, and ceilings constructed of smooth, easily cleanable surfaces;

(e) Have adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls;

(f) Have washing, cleaning, plumbing, toilet, and locker facilities to allow for:

1. Sanitary operation;
2. Cleaning of facilities, equipment and utensils; and,
3. Personal cleanliness; and,

(g) Have fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination.

(3) Equipment requirements.
Equipment, machinery and utensils used in manufacturing, processing, packaging, or relabeling of cosmetics must be specifically designed and constructed for the intended purpose to prevent corrosion, accumulation of static material, and adulteration with lubricants, coolants, dirt, and sanitizing agents. The equipment must be:
(a) Maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants;
(b) Constructed to facilitate adjustment, cleaning, and maintenance;
(c) Constructed to ensure accurate measuring, mixing, and weighing operations;
(d) Calibrated regularly or checked according to a standard operating procedure with results documented; and,
(e) Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately.

(4) Personnel requirements.
(a) Personnel supervising or performing cosmetics manufacturing must have the education, training, experience, or combination thereof, to perform their assigned functions.
(b) Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces must wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints).
(c) Personnel must maintain adequate personal cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds).
(d) Eating food, drinking beverages, or using tobacco must be restricted to designated areas away from storage and processing areas.
(e) All personnel and visitors must be supervised while in the manufacturing facility.
(f) Only authorized personnel shall be allowed access into production, storage, and product control areas.

(5) Raw materials requirements.
Raw materials must be identified, stored, examined, tested, inventoried, handled, and controlled. In particular, raw materials must be:
(a) Stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.);
(b) Held in closed containers and stored off the floor;
(c) Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine);
(d) Sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage; and,
(e) Specifically identified and controlled to prevent the use of materials that would be injurious to users if such material were incorporated into a cosmetic product and such product were used under the conditions of use prescribed in the labeling or advertisement of the product or under such conditions as are customary or usual.

(6) Water requirements.
(a) There must be established procedures for ensuring that the water used as a cosmetic ingredient is being tested or monitored regularly.
(b) The entire system for supplying water used as a cosmetic ingredient must be set up to avoid stagnation and risks of contamination (this system shall be routinely cleaned and sanitized according to a standard operation procedure that ensures no biofilm build-up).

(7) Product requirements.
Cosmetic manufacturers shall develop and maintain written manufacturing and control standard operating procedures addressing formulations, processing instructions, in-process control methods, packaging instructions, and instructions for operating equipment; the procedures must include provisions to ensure that:
(a) The selection, weighing, and measuring of raw materials and the determination of finished yield are verified;
(b) Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification or designation, stage of processing and control status;
(c) There are measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;
(d) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;
(e) The tamper-resistant packaging and labeling for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25;
(f) The storage and handling of packaging materials that are intended to come into direct contact with the product prevent selection errors and microbiological or chemical contamination; and,
(g) Finished product packages bear permanent, unique lot or control numbers and there is a coding system that corresponds to these numbers.
(8) Laboratory controls.
Cosmetic manufacturers shall develop and maintain laboratory controls addressing sample collection techniques, product development specifications, test methods, laboratory equipment, and technician qualifications; the laboratory controls shall include provisions to ensure that:
(a) Raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example, physical and chemical properties), microbial contamination, and hazards or other chemical contamination; and,
(b) Returned cosmetics are examined for deterioration, contamination, and compliance with the manufacturer’s product development specifications.
(9) Internal audit requirements.
Cosmetic manufacturers must have internal audit procedures that ensure:
(a) Internal audits are conducted randomly and on demand for a specific reason;
(b) Internal audits are conducted by individuals who do not have direct responsibility for the matters being audited;
(c) All observations made during the internal audit are evaluated and shared with management, production, quality control, and lab personnel who are responsible for developing and implementing corrective measures; and,
(d) Internal audit follow-up confirms the completion or implementation of corrective actions.
(10) Complaints, adverse events and recall requirements.
Cosmetic manufacturers must have standard operating procedures sufficient to:
(a) Facilitate the receipt, processing, evaluation and follow up on written and oral complaints;
(b) Facilitate the identification and retrieval of reported adverse incidents involving allegations of bodily injury or harm;
(c) Facilitate the effective and efficient identification and recall of products, including market withdrawal; and,
(d) Ensure notification of adverse incidents and product recalls to state and federal regulatory agencies; such notification shall be no later than 30 calendar days of receipt of the adverse incident and no later than 10 calendar days where the manufacturer has declared a product recall.

Rulemaking Authority 499.05 FS. Law Implemented 499.05, 499.008, 499.009 FS. History–New 7-1-96, Formerly 10D-45.0505, 64F-12.010, Amended 7-5-15.

61N-1.011 Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized.
(1) The exemption from the definition of wholesale distribution in Section 499.003(53)(b)2., F.S., for “emergency medical reasons” includes:
(a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;
(b) Transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical service provider licensed under Chapter 401, F.S., for use in the treatment of persons transported to that health care entity to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person or to immediately restock prescription drugs on the vehicle which have become unsuitable for use. This exception does not extend to the stocking of supply inventory or for warehousing of prescription drugs used by emergency medical service providers;
(c) Emergency transfers of prescription drugs as authorized in Rule 59A-4.112, F.A.C., for nursing homes or Rule 64B16-28.6021, F.A.C., of the Florida Board of Pharmacy; or

(d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy or to a health care entity to alleviate a temporary shortage, but not for the regular and systematic supplying of that prescription drug;

(e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:
   1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and
   2. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site;
   3. The prescription drugs are delivered to a pharmacy licensed under Chapter 465, F.S.;

(f) Transfers of prescription drugs by or on behalf of the Department of Health to the medical director of an advanced life support service provider, licensed under Chapter 401, Part III, F.S., and for further distribution to an emergency transport vehicle operated by the advanced life support services provider, for use in the treatment of persons in need of emergency medical services;

(h) Transfers of prescription drugs by or on behalf of the Department of Health to a health care entity authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health;

(i) Transfers of prescription drugs by or on behalf of the Department of Health to a community pharmacy authorized to purchase prescription drugs, for dispensing to persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by Section 499.005(21), F.S., provided:

(a) The hospital, health care entity or charitable institution forwards a copy of the documentation for the return to the manufacturer of the product. This documentation must at a minimum comply with the requirements of Rule 61N-1.012, F.A.C.; and

(b) The value of any credit, refund, or exchange for the returned product does not exceed the purchase price or, if a donation, the fair market price of the returned product.

(c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping as set forth in Section 499.0121, F.S.; and written documentation showing that these conditions were or were not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

3) A person authorized to possess non-dispensed prescription drugs can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to
charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 61N-1.008(2)(c), F.A.C.

(4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license or permit number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by Section 499.0121(6)(a), F.S.

Rulemaking Authority 499.003(53)(b), 499.012, 499.03, 499.05 FS. Law Implemented 499.003(53)(b), 499.012, 499.03, 499.05 FS. History–New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99, 4-17-01, 1-1-04, 10-4-07, 12-13-09, 6-8-10, Formerly 64F-12.011.

61N-1.012 Records of Drugs, Cosmetics and Devices.

(1) (a) Records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person’s receipt or acquisition to sale or other disposition of the product or component. A complete audit trail includes records which document each transaction or step in the receipt, manufacture, shipping, transfer, or other steps in the channel of trade of that person, whether or not physical possession or handling of the product or component occurs. At a minimum, records shall consist of invoices from the supplier or source which documents acquisition of each product by the person and invoices of sale or other transfer by the person to the recipient. Retail sales transactions to the consumer of over-the-counter drugs, non-restricted devices, or cosmetics are exempt from the requirements of this rule. Additional recordkeeping is required for persons permitted by the department as further stated in this rule.

(b) A person engaged in the distribution of drugs, devices, or cosmetics is not required to maintain documentation from a common carrier that the designated recipient received the product shipped; however, the person must obtain such documentation from the common carrier and make it available to the department upon specific request of the department.

(2) Any person engaged in the manufacture of prescription drugs, the wholesale distribution of prescription drugs, or otherwise receiving or distributing prescription drugs must maintain records as follows:

(a) For each step in the channel of trade, records containing the information required by Section 499.0121(6)(a), F.S., and the Florida permit or license number which authorizes the source to possess and transfer prescription drugs in or into Florida must appear on one document. If delivery of prescription drugs is made to a person other than the purchaser, the name, address or location where the prescription drugs are delivered, and the state license, permit or registration number for that location must be included also.

(b) The state permit or registration number of the purchaser may be omitted if the prescription drugs are exported; but a validated airway bill, bill of lading or other appropriate documentation must be maintained to evidence the exportation of the product.

(c) Invoices must reflect the amount billed per prescription drug product.

(d) Records to document the distribution of prescription drugs required by Section 499.0121(6), F.S., and this rule are to be created during the transaction (i.e., at the time of order, receipt, processing, picking or shipping) and not retroactively created. A pharmacy or other person authorized to possess prescription drugs that transfers prescription drugs to an establishment performing reverse distribution services or destruction activities must prepare or have prepared an inventory or other record of the prescription drugs so transferred prior to the prescription drugs leaving the premises. In addition to the name, address, and license number of the sender and the name, address, and license number of the receiving establishment, the record must include the elements set forth in paragraph 61N-1.023(3)(a),
F.A.C.

(e) Inventory. A complete and accurate record of all stock of prescription drugs on hand must be made annually by establishments permitted under Chapter 499, F.S. A physical inventory must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis. Significant inventory discrepancies must be investigated and handled in accordance with written policies and procedures of the establishment. In addition, no later than July 17, 2006, each wholesale distributor shall submit to the department an inventory of drugs it has on hand as of June 30, 2006.

(f) Inventory existing as of June 30, 2006. A wholesale distributor permitted under Section 499.012, F.S., that has purchased a prescription drug on or before close of business June 30, 2006, without the pedigree required by Section 499.01212, F.S., may distribute such drug provided the wholesale distributor submits to the department an inventory of such drugs no later than July 17, 2006, conforming to paragraph (2)(e) above and provided further that such drugs are otherwise in compliance with the provisions of Sections 499.001 through 499.081, F.S. Inventories shall be submitted to the department in written form, email, facsimile, or electronic media excluding a web page. The department will consider the submittal to be a trade secret as defined by Section 812.081(1)(c), F.S., provided that the sending wholesale distributor complies with the requirements of subsections 61N -1.021(1) and (2), F.A.C.

(3) Pedigree Papers.

(a)1. The pedigree papers required by Section 499.01212, F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner’s; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

2. A copy of the pedigree paper must be maintained by each wholesale distributor preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesale distributor preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesale distributor serves as the repository of its customer’s pedigree, the wholesale distributor must specify on the customer’s invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.

(b) If a wholesale distributor uses the statement contained in Section 499.01212, F.S., “This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer” the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(c) Beginning July 1, 2006, “Pedigree Paper (Distribution History of Prescription Drugs),” either Form DBPR 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DBPR 2129 must be used to comply with the requirement in Section 499.01212, F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either “Prescription (legend) Drug Pedigree – Repackager” Form DBPR 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DBPR 2135. A wholesale distributor that further distributes a repackaged prescription drug must include in the pedigree the information related to the repacked drug contained in Form DBPR 2135 or the electronic record that contains all the elements of Form DBPR 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.01212, F.S., at the discretion of the wholesale distributor. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices. Additional information to that required by forms DBPR
2129 and DBPR 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.

(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesale distributor providing the pedigree paper.

(e) Effective March 1, 2004, a pedigree paper under Section 499.01212, F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record. A prescription drug wholesale distributor that receives or prepares a pedigree paper under Section 499.01212, F.S., and this chapter that traces the previous distributions of a prescription drug back to a prescription drug wholesale distributor that is not listed on the department’s website as an authorized distributor of record for the drug’s manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesale distributor is an authorized distributor of record in accordance with the criteria of Section 499.01212, F.S.

(f) Returns.

1. When a distribution of a prescription drug by a wholesale distributor to a pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that prescription drug by the recipient to the wholesale distributor need not be reflected in a pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within fourteen calendar days after the date of receipt of the original shipment:
   a. The recipient ships the specific unit of the prescription drug back to the wholesale distributor from which that specific unit was purchased; or
   b. The recipient transmits a documented communication to the wholesale distributor from which the prescription drug was purchased stating the recipient’s intent to return the shipment in accordance with the wholesale distributor’s prescribed written policies and procedures and the wholesale distributor communicates authorization for return of the product.

2. Any returns to a wholesale distributor that are not within the scope of subparagraph 1. shall be reflected in a pedigree paper for any subsequent wholesale distributions of the returned drug product to the extent required by Section 499.01212, F.S.

3. A recipient that returns a prescription drug to the wholesale distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product:
   a. That the specific unit (exact unit) being returned was purchased from the receiving wholesale distributor (including the corresponding sales invoice number and the date of the sale from that wholesale distributor to the authorized recipient); and,
   b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser’s custody and control.
   c. The written declaration shall be printed or typed at the end of or immediately below the statements in subparagraphs 3.a. and 3.b. and shall state: “Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true,” followed by the signature of the person making the declaration.

(g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.

(h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesale distributor consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., (and that wholesale distributor provides a pedigree to its customer consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., the wholesale distributor must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesale distributor provides to its customer.
(i) A wholesale distributor that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesale distributor prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (3)(h) above.

(j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.01212, F.S., to provide a pedigree paper upon distribution of the manufacturer’s prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on its relationship with the manufacturer.

(k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree that complies with Section 499.01212, F.S., is not available, when the prescription drug is required immediately to treat a specific patient with a life-threatening medical condition or a medical condition that will result in serious bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to the supplying wholesale distributor(s) that the emergency meets this rule paragraph’s requirements and the supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.

(4) Retailers of veterinary legend drugs or medical oxygen must also maintain a prescription or other order of an authorized practitioner evidencing the authority of the purchaser or recipient to receive the veterinary legend drug or medical oxygen. A veterinary legend drug retailer must have the prescription prior to delivery of the drug to the customer. In the case of a medical oxygen retailer, the prescription or order for medical oxygen must be in writing and in the possession of the retailer within 30 days of delivery of the drug to the patient. An order or prescription for veterinary legend drugs or medical oxygen does not constitute authority for the retailer to sell to the purchaser beyond 12 months from the date of the original sale.

(5) A copy of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and Chapter 61N-1, F.A.C., Regulations for Drugs, Devices and Cosmetics, must be at the permitted establishment.

(6)(a) Records for permittees not physically located within the state may be maintained at a central location outside of the state but must be made available for inspection at a permitted establishment or at the department’s address within 2 working days after a request for inspection.

(b) Records for permittees located in the state or persons located in Florida and required to be permitted under Chapter 499, F.S., may be stored by computer or other electronic means at a central location inside or outside of the state, but must be readily available and immediately retrievable, i.e., subject to inspection at the permitted establishment during the inspection.

1. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to Sections 499.001-.081, F.S., in that person’s name.

2. If not maintained at a central location, records must be maintained at the permitted location or, if not otherwise permitted, at the address reflected on the product registration.

3. A permitted establishment in Florida that maintains records at a location outside of the state must have a method, such as computerized access, to make records readily available and immediately retrievable. These records must also be made available at the permitted establishment for copying or reproducing within two working days after a request.

4. An establishment permitted at an address outside of the state must make records available for inspection within two working days after a request.

(c) Records for permittees may be copied or reproduced by the department or the Florida Department of Law Enforcement.

(d) If hard copies (originals or true copies) of required records are not maintained at the permitted establishment in Florida, the department or Florida Department of Law Enforcement must be able to review automated records for
any and all records required to be maintained under Chapter 499, F.S., without requesting a specific source, recipient, product, date, etc.

(7) Except as provided in Section 499.012(2)(e), F.S., and paragraph (3)(b) of this rule, records of other persons not required to be permitted but subject to regulation under Chapter 499, F.S., must be made available to the department or the Florida Department of Law Enforcement within five business days of the request for inspection, copying, or reproduction.

(8) Records involving drugs, devices, or cosmetics may be maintained by electronic methods, such as computers or imaging devices. Originals or true copies of required records documentation must be maintained by the person involved in the transaction, including brokers and agents. If electronic methods are used to maintain records related to prescription drugs and these methods do not maintain a true copy of the original record, such as the actual image of the original document, then the security system of the permittee must provide protection against tampering with computers or electronic records.

(9) Documentation provided to the department pursuant to an inspection may not be altered or defaced in any manner to obstruct or conceal any required or other information recorded on the document.

(10) All required records must be retained for a period of two years following disposition of the drug, device or cosmetic, or three years after the creation of the records, whichever period is longer; and must be available to the department for such period or as long as records are retained if longer. Records must be retained beyond the retention period if the person has been notified that an investigation or inspection has been initiated by the department and the investigation has not been completed when the mandatory retention period expires.

(11) Manufacturers shall maintain formulas of drugs and cosmetics, including all ingredients, and shall make these available to the department upon request, either during an inspection or by certified mail.

(12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or business. A person permitted under Chapter 499, F.S., that also conducts other business activities not permitted under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other business activities. For the purpose of this rule, those operational systems required to be kept separate and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A Retail Pharmacy Drug Wholesale Distributor however, is not required to maintain its stock of prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription drugs which may be dispensed by a retail pharmacy.

(13) An establishment permitted to purchase or possess prescription drugs that has no records or has not done any business under the permit that would require such records, shall upon request, provide to the department a written statement to that effect.

(14) The recordkeeping requirements of this subsection do not apply to the prescription dispensing records of a pharmacy or to the patient medical records of a licensed practitioner; however, such records may be required to be produced pursuant to a subpoena issued by the department under Section 499.002(3), F.S.

(15) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drugs, including prescription drug samples, pursuant to Section 499.003(53)(b)5., F.S., must prepare and maintain a donation record that includes at a minimum:

(a) The donor’s name, address, telephone number, the practitioner’s state license number, and D.E.A. number if a controlled substance is donated;
(b) The manufacturer, brand name, strength, and dosage form of the product; the quantity donated by lot number; and the expiration date of the product;
(c) The date of the donation;
(d) The name, address, and state license number that authorizes the possession of prescription drugs by the charitable organization, if applicable; and,
(e) Within 48 hours of receipt, excluding holidays and weekends, the recipient charitable institution must provide a written receipt to the donor acknowledging receipt of the donated prescription drugs.
(16) Establishing an ongoing relationship pursuant to Section 499.01212, F.S. A wholesale distributor that is not listed as an authorized distributor of record on the list submitted to the department by a prescription drug manufacturer may request the department add the wholesale distributor to the department’s website of authorized distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.01212, F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.

(a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesale distributor establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:
   a. The most recent audited financial report that includes an Income Statement or Statement of Profit/Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities); or
   b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year; or
   c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales, excluding customer returns; and,

2. For each manufacturer for whom the wholesale distributor claims authorized distributor of record status, submit both subparagraphs a. and b. to document that the wholesale distributor annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer’s prescription drug products directly from that manufacturer.
   a. A computerized listing of all of a manufacturer’s prescription drugs purchased by the wholesale distributor during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled; and,
   b. (I) A computerized listing of all purchases of a manufacturer’s prescription drugs directly from the manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesale distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer; or
   (II) Copies of the manufacturer’s sales invoices of prescription drugs to the wholesale distributor. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesale distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

3. Each wholesale distributor establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group’s ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesale distributor establishment, must submit the names and address of all member wholesale distributor establishments of the affiliated group. In addition, each wholesale distributor establishment must either:
   a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as the affiliated group upon which the eligibility criteria for the affiliated group was met; or
   b. Hold a valid prescription drug wholesale distributor permit or out-of-state prescription drug wholesale distributor permit; or
permit issued under Chapter 499, F.S.
(b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to
document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs
pursuant to Section 499.01212, F.S.
1. To document total annual prescription drug sales of $100 million or more submit either:
a. The most recent audited financial report that includes an Income Statement or Statement of Profit/Loss that
indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial
report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities); or
b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had
total annual prescription drug sales of $100 million or more in the most recent fiscal year; or
c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month
period based on the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail
should include the invoice number, invoice date, customer name, and total invoice amount related to prescription
drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales,
excluding customer returns.
2. For each manufacturer for whom the wholesale distributor claims authorized distributor of record status, submit
sub-subparagraph a., b., or c. to document that the wholesale distributor has a verifiable account number issued by
the manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the
verifiable account number.
a. If the wholesale distributor is a member of an affiliated group and all purchases from that manufacturer are made
at a central location for the wholesale distributor, copies of at least 12 invoices dated during the previous 12 months
from the date the information is submitted, which invoices document purchases of prescription drugs, at least one
unit of which on each invoice was not returned, under that central account number but shipped to the wholesale
distributor’s address for whom the authorized distributor of record status is claimed. A statement must be provided
that the invoices document purchases of prescription drugs for the wholesale distributor for whom the authorized
distributor of record status is claimed and that the wholesale distributor did not return to the manufacturer at least
one unit of the prescription drugs on each invoice.
b. If the wholesale distributor is a member of an affiliated group and all purchases from that manufacturer are made
at a central location and received at a central location for the wholesale distributor, copies of at least 12 invoices
dated during the previous 12 months from the date the information was submitted, under the same account number
which is clearly assigned to the wholesale distributor at the permitted address. Each invoice must document the
purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement
must be provided that the invoices document purchases of prescription drugs by that central location and that the
central location or wholesale distributor for which the drugs were obtained did not return to the manufacturer at least
one unit of the prescription drugs on each invoice, and that the central location shipped at least 12 times to the
individual wholesale distributor for whom the authorized distributor of record status is claimed during the 12 months
based on the fiscal year or designated timeframe.
c. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from the
date the information was submitted, under the same account number that is clearly assigned to the wholesale
distributor at the permitted address. Each invoice must document the purchase of prescription drugs, of which at
least one unit identified on the invoice was not returned. A statement must be provided that the invoices document
purchases of prescription drugs by that wholesale distributor and that the wholesale distributor did not return to the
manufacturer at least one unit of the prescription drugs on each invoice.
(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”)
purposes under Sections 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the records required
pursuant to Section 499.0121(6), F.S., must identify the R&D requirements, acquisition schedule and use of each
drug acquired relative to anticipated and ongoing R&D activities. These records must be created in advance of or
within 30 calendar days of the particular R&D activities, and are subject to inspection under Section 499.051, F.S.
Non-clinical/pre-clinical R&D quantities must be updated annually, and clinical quantities must be updated
semiannually. The researcher must maintain all other records required under Chapter 499, F.S., including, without limitations, Section 499.01(3) or (4)(b), F.S., and applicable federal laws.

Rulemaking Authority 499.05, 499.0121 FS. Law Implemented 499.01, 499.012, 499.0121, 499.01212, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067 FS. History—New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.53, Amended 1-26-99, 4-17-01, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012, Amended 3-4-13, 11-16-15.

61N-1.013 Prescription Drugs; Receipt, Storage and Security.

(1) Establishments in which prescription drugs are stored, manufactured, repackaged, kept, held, used, sold, stored, offered for sale, or exposed for sale, shall be secured against unauthorized entry or unauthorized access to prescription drugs when establishment personnel are not present.

(a) Establishments permitted under Chapter 499, F.S., that are authorized to take possession of prescription drugs, other than medical oxygen, must be secured by an alarm system which functionally and practically provides a deterrent to unauthorized entry to the establishment or the area where the prescription drugs are held or stored.

(b) Prescription medical oxygen may be stored outside in an area surrounded by a fenced enclosure with a lock which must be secure when authorized persons are not present. Other compressed medical gases must be stored in accordance with paragraph (a).

(2) (a) While not being used to make deliveries, a vehicle of a permittee containing prescription medical oxygen must be parked at the permitted establishment and either locked inside a fenced compound or secured by a vehicle alarm system. A vehicle containing prescription medical oxygen may only be parked at a residence temporarily while the vehicle is making deliveries or while “on call” for emergency deliveries.

(b) When a vehicle used for prescription drug wholesale distributions or for distributions subject to a restricted prescription drug distributor’s permit contains prescription drugs and is not being used to make deliveries, it must be parked inside a building secured by an alarm system.

(c) A residence cannot be used to store any prescription drug which has not been dispensed, unless a natural person residing at that residence is licensed or otherwise authorized to possess prescription drugs.

(3) (a) The storage temperature definitions in the U.S.P. are incorporated by reference herein. If no storage and temperature requirements are set forth by the manufacturer in the labeling or in the U.S.P., prescription drugs other than compressed medical gases must be stored at controlled room temperature. Compressed medical gases, unless otherwise indicated, may be stored in a manner so that they are protected from freezing and are not stored at or near excessive heat or open flame.

(b) All establishments permitted under Chapter 499, F.S., that handle prescription drugs other than medical gases, must, in the absence of electronic monitoring devices, mount two thermometers in the immediate area of the stored prescription drugs. For purposes of this provision, immediate area of the stored prescription drugs is within six (6) feet of the prescription drugs in storage. One thermometer will be mounted in the warmest area of the stored prescription drugs and the other thermometer will be mounted in the coolest immediate area of the stored prescription drugs.

(c) A record must be maintained recording the date; time; thermometer one temperature; thermometer two temperature; and the initials of the person recording the data or reviewing the data if electronically monitored. This record and temperature reading must be recorded at least five (5) days each week with the temperature readings taken between 2:00 p.m. and 4:00 p.m. (EST). Alternate times may be approved by the department in writing. This record must be kept on file by the facility for at least two years.

(d) Facility requirements for the storage and handling of prescription drugs.

1. An applicant for an initial prescription drug wholesaler permit must have a facility that is large enough to store the estimated quantity of prescription drugs the applicant intends to possess under its initial application to comply with the requirements of Section 499.0121(1), F.S. An applicant for renewal of a prescription drug wholesaler permit must have a facility that is large enough for the ongoing operations of the wholesale establishment based on the prior year’s volume of activity with prescription drugs, which may be modified for reasonable fluctuations in inventory management for the current year. These determinations will be based on the type of prescription drugs the applicant
possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the facility must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

2. An applicant for an initial prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity large enough to store the estimated quantity of prescription drugs that might require refrigeration or freezing that the applicant intends to possess under its initial application to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. An applicant for renewal of a prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity that is large enough for the ongoing operations of the wholesale establishment based on the prior year’s volume of activity with prescription drugs that required refrigeration or freezing, which may be modified for reasonable fluctuations in inventory management for the current year, to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. These determinations will be based on the type of prescription drugs the applicant possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess that might require refrigeration or freezing. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the refrigeration and freezer capacity must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

3. Prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Sections 499.01(3) and (4)(b), F.S., and paragraph 61N-1.001(2)(n), F.A.C., must be physically segregated from all other products intended for manufacturing, compounding, dispensing, or administration. In a manufacturer’s establishment, these drugs must also be stored and maintained in a separate and clearly designated area.

4) Quarantine.
   (a) A quarantine section shall be clearly marked and designated separate and apart from any other place where drugs are stored so that products therein shall not be confused with usable products being held for sale. Any prescription drug stored outside the quarantine area is a product held for sale or other distribution.
   (b) The requirement of Section 499.0121(5)(b), F.S., that prescription drugs must be quarantined if damage has occurred to the immediate or sealed outer or sealed secondary containers means: a prescription drug must be quarantined if obvious damage, determined by a visual inspection of the exterior of the product’s packaging, has occurred to any part of the packaging that is or may be in direct contact with the dosage form of the drug or any additional part of the packaging which is provided to prevent adulteration of the drug in addition to “containing” the product.
   (c) A person who handles both prescription drugs and over-the-counter drugs or medical devices may have one quarantine section; however, the storage requirements for prescription drugs must be followed.

(5) Examination of Prescription Drugs; Physical Product and Records.
   (a)1. Every person receiving prescription drugs other than the consumer receiving dispensed prescription drugs pursuant to Chapter 465, F.S., has a duty to examine the product to prevent acceptance of prescription drugs that are unfit for distribution or use. The extent of the examination should be predicated on the conditions surrounding the transaction, including but not limited to any previous sales of the product, i.e., purchase and delivery is not direct from the manufacturer; the conditions of transport; and environmental conditions to which the product may have been subjected.

2. A wholesaler, chain pharmacy warehouse, or person authorized to administer or dispense a prescription drug that physically receives a prescription drug must verify that the prescription drug received matches the prescription drug identified on the corresponding pedigree. The corresponding pedigree document shall contain all of the required information described in Sections 499.01212(2)(a) or (b), F.S. as applicable, including the information required in the forms described in subsection 61N-1.012(3), F.A.C., for those distributions that are not eligible for the use of the direct purchase pedigree.
   (b) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of misbranded drugs, adulterated drugs or prescription drugs that are otherwise unfit for distribution. If visual examination of the shipping container or other conditions surrounding the transaction suggest possible
misbranding or adulteration, the person has a duty to examine further the contents or conditions of sale.

(c) Prescription Drug Wholesalers must employ personnel who can perform product examinations. Once the Prescription Drug Wholesaler has inspected the shipped drugs and elected to accept them, the wholesaler is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition, unless responsibilities are modified by contract.

(d) Authentication.

1. A prescription drug wholesaler may use any, all, or any combination of the following methods to authenticate each transaction on a pedigree paper and must maintain the corresponding documentation regarding the authentication for the method used:

a. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include at a minimum a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in sub-subparagraph b., c., or d. below. Each wholesaler shall establish and adhere to policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically valid standards.

b. Telephone call to the seller. Documentation requirements include a signed statement by the person placing the telephone call identifying the person’s name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

c. E-mail communication with the seller. Documentation requirements include a copy of the e-mail that identifies the person’s name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

d. Verification of the transaction per a web-based system established by the seller or an independent person that is secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transaction(s). Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the web site and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the (dated) web site page that confirms the sales transaction between the parties, including the date of the transaction and the quantity of prescription drugs involved in the transaction.

e. Receipt of a legible and unaltered copy of a previous transaction’s pedigree paper that had been signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in sub-subparagraph b., c., or d. above. Each wholesaler shall establish and adhere to policies and procedures for the random verification of the authenticity of these copies of pedigrees according to statistically valid standards.

f. Receipt of a pedigree in an electronic form from an automated system that complies with this sub-subparagraph that was successfully opened and decrypted by an automated system that complies with this sub-subparagraph. In order to rely on receipt of an electronic pedigree without employing additional authentication methods as set forth in sub-subparagraphs a.-e.,

(I) The system used to digitally sign and electronically authenticate the electronic pedigree must at a minimum support the following digital signature standards or future revisions governed by the National Institute of Standard and Technology (NIST):

(A) FIPS 140-2 validated cryptographic module which is hereby adopted by reference;
(B) FIPS 186-2 validated digital signature system which is hereby adopted by reference;
(C) FIPS 180-2 validated hash function which is hereby adopted by reference;
The system must employ controls to ensure the security and integrity of the private key so that it cannot be accessed by someone other than the certificate holder. At a minimum, the system must:

A) Control the activation of the private key with an authentication mechanism;
B) Employ a ten-minute inactivity time period after which the certificate holder must re-authenticate to access the private key;
C) When the signing module is deactivated, clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key;

III) The system must communicate with the Certification Authority directory, either each time authentication and validation steps in sub-subparagraph (IX) below occur or at least on a daily basis to download information to perform the authentication and validation which will occur on that day.
IV) The system must have a time system that is within five minutes of the official NIST time source and date and time stamp any and all digital signatures.
V) The system must archive digitally signed files unaltered, including the original hashes and reference to the public keys, in a manner that facilitates retrieval of the record consistent with the recordkeeping requirements.
VI) The system must prevent issuance of an outgoing pedigree paper if the total quantity of prescription drugs distributed in all pedigrees exceeds the quantity of prescription drugs received in the corresponding incoming electronic pedigree.
VII) The system must maintain a history file of any outgoing electronic pedigree that is subsequently voided or altered and notify the recipient that the pedigree sent to it was voided or altered.
VIII) The system must maintain a history file of any incoming notification received pursuant to sub-sub-sub-subparagraph (VII) above that a pedigree was voided or altered and prevent the issuance of an outgoing pedigree using a pedigree that was voided or altered.
IX) The system must verify or perform the following:
A) Each transaction on the electronic pedigree must be digitally signed using certificates issued through a public key infrastructure system authorized by the department.
B) The electronic pedigree must contain each prior transaction digitally signed and unaltered, including the original hash and reference to the public key, with the new transaction information appended to the new document and the entire resulting pedigree digitally signed, including the resulting hash and reference to the public key.
C) The system must check the certificate expiration date of each signed transaction and compare it against the date and time that the transaction was signed to determine that the certificate has not or had not expired at the time the record was signed.
D) The system must check the digital signature for each signed transaction against the Certificate Authority’s directory and the Certificate Revocation List and verify whether the certificate holder is or was authorized to sign electronic pedigrees at the time the transaction was signed.
E) The system must decrypt each digital signature for each signed transaction in the pedigree using each sender’s public key and compare it against the message digest to determine that the record has not been altered since it was originally signed.
F) The system must require that all authentication and validation steps in the preceding paragraphs are carried out prior to allowing the acceptance of the transaction. The system should not allow the further processing of any transaction that has failed to pass any authentication or validation step.
(X)A) The manufacturer must initiate the pedigree; or, until such time as the manufacturer initiates a pedigree to the wholesaler, the wholesaler that purchased the prescription drug from the manufacturer must imbed a copy of the sales invoice or the manufacturer’s EDI transmission or Advance Ship Notice (ASN) that contains all required data elements for a complete audit trail as set forth in Rule 61N-1.012, F.A.C., related to that wholesaler’s acquisition of the prescription drug from the manufacturer. Price information related to the transaction may be redacted from the imbedded copy of the sales invoice, the EDI transmission, or the ASN.
B) If a pedigree complies with all provisions within sub-subparagraph f. except for sub-sub-sub-subparagraph (X)A) above, then a prescription drug wholesaler must use another method authorized by this rule to authenticate the distribution from the manufacturer to the first wholesaler. Subsequent distributions may be authenticated in
accordance with sub-subparagraph f.

2. If a pedigree cannot be authenticated because of a clerical error, the pedigree must be corrected by the sender.

3. If a pedigree cannot be authenticated and the reason is other than a clerical error, or the reason cannot be satisfactorily ascertained based on preliminary investigation, the prescription drug for which the pedigree cannot be authenticated must be quarantined and the department notified within 3 business days.

4. A purchasing wholesaler may use a written contract between the purchasing wholesaler and its wholesale supplier, which is a primary wholesaler as defined in Section 499.012(1)(d), F.S., that requires that all prescription drugs distributed to the purchasing wholesaler by the wholesale supplier must be purchased by the wholesale supplier from the manufacturer. If this method is used to authenticate a pedigree, the purchasing wholesaler shall establish and adhere to policies and procedures for the random verification of the authenticity of the pedigrees that disclose the supplier wholesaler purchased the prescription drug from the manufacturer according to statistically valid standards.

5. The following persons in Florida that are authorized to purchase or possess prescription drugs are not required to authenticate a pedigree paper received from a person authorized by law to distribute prescription drugs to that person:
   a. A licensed pharmacy, unless it is also permitted as a retail pharmacy wholesaler and will engage in the wholesale distribution of that drug, or unless it is a member of an affiliated group and will distribute a prescription drug purchased or received directly from a prescription drug wholesaler that is not also a member of its affiliated group to another member of its affiliated group;
   b. A medical practitioner; or

6. In order to authenticate pedigrees, a manufacturer of a prescription drug that is sold or distributed in Florida must make available upon request information relevant to authenticating a pedigree for that drug regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

7. Any wholesaler or repackager required under Chapter 499, F.S., to receive a pedigree paper must authenticate the pedigree pursuant to Section 499.0121(4), F.S., notwithstanding the absence of a pedigree paper or authentication by persons in the distribution chain not subject to the requirements of Chapter 499, F.S.

(6) Any establishment that is permitted as a prescription drug wholesaler or repackager must notify the department in writing within three working days of discovery of a significant loss or theft of prescription drugs. Whether a loss or theft is significant is to be based on the prescription drug wholesaler’s written policies and procedures that may take into account the actual quantity in relation to the type or size of the business; any pattern of losses or thefts; and local trends or other indicators of the diversion potential. Notification to the Drugs, Devices and Cosmetic Program may be made by facsimile to (850)413-6982 and must include at a minimum, identification of the permitted establishment reporting the loss or theft; a complete identification of the prescription drug(s) involved, including but not limited to the name of the manufacturer or distributor reflected on the label of the products, the dosage form, strength, container size, the quantity of each, the lot numbers if known; a brief description of the circumstances surrounding the theft or loss; and a contact person’s name and telephone number to provide additional information.

(7) Due Diligence Inspection. With respect to the inspection required under Section 499.0121(12)(e), F.S., a prescription drug wholesaler may rely on a due diligence inspection performed by a person that is independent of both wholesalers for purposes of the requirement in Section 499.0121(12)(e), F.S.

Rulemaking Authority 499.0121(1), 499.05 FS. Law Implemented 499.006, 499.007, 499.01, 499.0121, 499.028(6), 499.052 FS. History–New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-99, 4-17-01, 1-1-04, 1-19-06, 11-18-07, Formerly 64F-12.013, Amended 11-16-15.

61N-1.014 Devices or Over-the-Counter Drugs; Storage and Receipt.
(1) Establishments where devices or over-the-counter drugs are manufactured, packaged, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale or use must do so under proper conditions of temperature as required by the manufacturer’s labeling of the product or according to the U.S.P. If no temperature requirements as described above are indicated, over-the-counter drugs must be stored at temperatures no higher or lower than room
temperature as defined in the U.S.P.

(2) Establishments where devices or over-the-counter drugs are manufactured, packaged, repackaged, stored, stocked, distributed, used, sold, offered for sale, exposed for sale, or kept for sale or use shall maintain a “quarantine” section for those products which are deteriorated, outdated, misbranded, or otherwise unfit for use. This “quarantine” section shall be clearly marked and designated separate and apart from other sections so that products therein shall not be confused with usable products. Any device or over-the-counter drug stored outside of the quarantine area will be considered as a product held for sale or other distribution. A person who handles both prescription drugs and devices or over-the-counter drugs may have one quarantine section; however, the storage requirements for prescription drugs must be followed.

(3) Every person receiving devices or over-the-counter drugs except through a retail sale has a duty to examine the product to prevent acceptance of devices or over-the-counter drugs that are adulterated, misbranded or otherwise unfit for distribution or use.

(4) Establishments in which devices or over-the-counter drugs are manufactured, packaged, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale or use must be maintained in a clean and orderly manner to prevent the products from becoming contaminated with filth or injurious to health.

Rulemaking Authority 499.05 FS. Law Implemented 499.004, 499.006, 499.007, 499.013 FS. History – New 7-1-96, Formerly 10D-45.05355, Amended 1-26-99, Formerly 64F-12.014.

61N-1.015 Licensing, Application, Permitting.
This section addresses the application and permitting requirements of persons regulated under Part I of Chapter 499, F.S.

(1) Any person that is required under Sections 499.001-.081, F.S., to have a permit shall apply to the department for the appropriate permit on forms indicated in this rule. Inquiries regarding requests for an application or licensing may be directed to The Department of Business and Professional Regulation, Drugs, Devices, and Cosmetics Program, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047 or telephone number (850)717-1800. Applications may be downloaded from the bureau’s web site at www.myfloridalicense.com.

(2) A permit is valid only for the name and address to which it is issued. The name in which a permit is issued will be changed, at no cost, upon notification to the department.

(a) The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

(b) A permit that authorizes the purchase of prescription drugs will not be issued in a name identical to the name used by any other establishment or licensed permit holder at that address authorized to purchase prescription drugs pursuant to Chapter 465, F.S., or the statutes regulating a practitioner authorized to purchase prescription drugs except:
1. A Restricted Rx Drug Distributor – Charitable Organization permit will be issued in the name of the charitable organization or health care entity, and
2. A Medical Oxygen Retailer permit may be issued in the name of a nursing home’s Class I Institutional Pharmacy permit.

(c) A person must be available for inspection at the permitted address during the business hours identified on the application form, holidays excluded. Permanent changes to these business hours must be communicated to the department in writing. At a minimum, these business hours must meet the following standards:
1. For an establishment applying for a permit or permitted as a prescription drug wholesaler or prescription drug wholesaler – broker only, the establishment must designate a minimum of 20 hours weekly between the hours of 8:00 a.m. and 5:00 p.m. EST, Monday through Friday, and at least one day of the week provide for four consecutive hours.
2. For an establishment applying for a permit or permitted only as a medical oxygen retailer and which does not transfill medical oxygen containers at the permitted establishment, the establishment must designate a minimum of four (4) hours weekly between the hours of 8:00 a.m. and 5:00 p.m. EST, Monday through Friday, and at least one day of the week provide for two consecutive hours. Furthermore if less than 10 hours weekly are designated, a
medical oxygen retailer must be available by telephone between the hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, to schedule an appointment within 24 hours of the department’s telephone call for an inspection during non-designated business hours.

3. Other applicants and permitted establishments must designate a minimum of 10 hours weekly between the hours of 8:00 a.m. and 5:00 p.m. EST, Monday through Friday, and at least one day of the week provide for two consecutive hours. These standards set forth minimum business hours and agents of the Department of Business and Professional Regulation and the Department of Law Enforcement may inspect, monitor, and investigate during other hours as authorized by law.

(3) On-site Inspections. Passing an on-site inspection is a prerequisite to issuance of a new permit for the following permit types: Prescription Drug Manufacturer, Device Manufacturer, Compressed Medical Gases Manufacturer, Over-the-Counter Drug Manufacturer, Cosmetic Manufacturer, Prescription Drug Wholesaler, Compressed Medical Gases Wholesaler, Freight Forwarder, Veterinary Prescription Drug Wholesaler located in Florida, Veterinary Legend Drug Retailer, Medical Oxygen Retailer, and Restricted Rx Drug Distributor permits for the Health Care Entity, Reverse Distributor, and Destruction facilities. However, the department may elect to perform an inspection of the Restricted Rx Drug Distributor – Charitable Organization, Government Program, or Institutional Research as a condition of permitting but an on-site inspection fee will not be assessed.

(a)1. A person permitted as a Prescription Drug Manufacturer that is applying for additional manufacturing permits, a Complimentary Drug Distributor permit, or a Prescription Drug Wholesaler permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permits.

2. A person permitted as an Over-the-Counter Drug Manufacturer that is applying for a Device Manufacturer permit or Cosmetic Manufacturer permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

3. A person permitted as a Cosmetic Manufacturer or Device Manufacturer that is applying for a Device Manufacturing permit or Cosmetic Manufacturing permit does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

(b) A person permitted as a Compressed Medical Gases Manufacturer that is applying for either a Compressed Medical Gases Wholesaler permit or a Medical Oxygen Retailer permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

(c) A person permitted as a Medical Oxygen Retailer that is applying for a Compressed Medical Gases Wholesaler permit at that address does not require another on-site inspection and is not required to pay the initial application/on-site inspection fee when applying for the additional permit. A person permitted as a Medical Oxygen Retailer that has the establishment registered with the FDA for transfilling activity which is applying for a Compressed Medical Gases Manufacturer’s permit at that address does not require another on-site inspection and is not required to pay the initial application/on-site inspection fee when applying for the additional permit.

(d) The department will request from the applicant written documentation to evidence compliance with the requirements of Chapter 499, F.S., when an on-site inspection cannot be completed within 30 days of receipt of a completed application for a permit requiring an on-site inspection or a written request for a change of address.

(4) Written policies and procedures as required by Chapter 499, F.S., and this rule chapter must be established prior to approval of a permit application. A prescription drug wholesaler that uses a system to digitally sign and electronically authenticate an electronic pedigree must have policies and procedures to protect the security over the digital signatures.

(5) Notification to the department regarding the change of address of a permitted establishment must be in writing. A Change of Address form is available on the department’s web site. Notification regarding the closing of a permitted establishment shall also include the name and address of a person to contact for up to two years after the closing of the business for access to required records.

(6) Manufacturer Permits.

(a) A prescription drug manufacturer’s permit, over-the-counter drug manufacturer’s permit, or device
manufacturer’s permit is not required for the manufacture of products that are in an FDA approved investigational program and that are not manufactured for clinical investigation (for actual use in or on humans or animals).

(b) A device manufacturer’s permit is required for an establishment that refurbishes medical devices for subsequent sale but is not required when the refurbishing is performed as a service for the owner of the medical device and the device is returned to the owner for further use.

(c) Application requirements for manufacturers and prescription drug repackagers located in Florida include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
2. File with the department a completed application for a permit using an original Form DH 1033, “Application for Permit Under Chapter 499, F.S.,” effective August 2004, which is incorporated by reference herein.
3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
5. Have an FDA establishment registration number, or unless the application is for a cosmetic manufacturer, provide documentation to the department supporting an exemption from FDA registration.

(d) Application requirements for Non-resident prescription drug (Rx) manufacturers.
1. A person may qualify as a Non-resident Rx drug manufacturer if
   a. The establishment is not located in Florida; and
   b. (I) The person and establishment physically manufacture a prescription drug either for itself or as a contract manufacturer; or
   (II) The person is the holder of an approved New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or New Animal Drug Application (NADA); or
   (III) The person and establishment is a private label distributor and the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or
   (IV) The establishment is the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer’s affiliated group or is a contract distribution site; or
   (V) The person and establishment import prescription drugs, including active pharmaceutical ingredients also referred to as bulk ingredients that are lawful in interstate commerce.
2. A non-resident Rx drug manufacturer that also distributes prescription drugs that it did not manufacture (as meeting one of the criteria above) will also need to apply for an out-of-state prescription drug wholesaler permit and meet all of the requirements for obtaining that permit.
3. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
5. Submit a photocopy of all permits or licenses issued to the applicant’s address which authorize the manufacture or possession of prescription drugs at that address, regardless of the issuing agency. If the issuing agency prohibits photocopying the permit or license, the applicant may submit a state verification of any permits or licenses issued to the applicant’s address.
6. If the non-resident Rx drug manufacturer is importing prescription drugs, FDA approval can be documented with:
   a. An NDA number for the product; or
   b. Evidence of an FDA establishment number for the manufacturing site and inclusion of the particular product on the manufacturer’s drug listing with the FDA; or
   c. For an active pharmaceutical ingredient, evidence that the manufacturer’s bulk drug substance is identified as an ingredient in an FDA approved finished product; or
   d. Other direct evidence of FDA authorization for the importation and commercial distribution of the product.

Updates to the list of prescription drugs being imported and documentation of FDA approval must be submitted to the department prior to importation of any prescription drug under the non-resident Rx drug manufacturer’s permit. It is the non-resident manufacturer’s responsibility to assure that it is only importing approved prescription drugs
into Florida and is complying with Section 499.023, F.S. Compliance with submission of the information required in this rule does not mean that the prescription drug does in fact comply with all provisions of the Federal Act and Chapter 499, F.S., and may be imported.

7. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

8. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(7) Wholesaler Permits.

(a) A person applying for or renewing a permit as a prescription drug wholesaler, or as a veterinary prescription drug wholesaler located in Florida, must have an area for the storage of prescription drugs under controlled room temperature and refrigeration, as required by paragraph 61N-1.013(3)(d), F.A.C., whether or not the person intends to wholesale prescription drugs requiring storage under controlled room temperature conditions or refrigeration; except that a person who will act as a broker only of prescription drugs may apply for a “broker only” designation on the Prescription Drug Wholesaler permit and then the requirement that the permitted address provide for “controlled room temperature” and refrigeration is waived. A “broker only” cannot take possession of prescription drugs under any circumstances.

(b) The Prescription Drug Wholesaler’s bond and the bond for an out-of-state prescription drug wholesaler will be transferred by the department to subsequent permits issued pursuant to renewal applications if the bond or other equivalent means of security is in a form that will allow for such transfer. The bond will be refunded without interest, consistent with the provisions of Section 499.012(2), F.S. In order for another means of security to satisfy the bond requirement, the security must be in a form that the applicant or permittee cannot revoke, withdraw, cancel, or otherwise reduce the department’s interest until the conditions upon which the bond can be refunded or released, as set forth in Section 499.012(2), F.S., have been satisfied. If the bond or other security is in a form that requires the department to initiate release of the bond or security, a prescription drug wholesaler or out-of-state prescription drug wholesaler should request in writing that the department release the bond or security within 45 days of satisfaction of the conditions in Sections 499.012(2)(a) and (c), F.S., that release department’s interest in the bond or other security. The department must initiate release of the bond or security within 10 working days of satisfaction of the conditions in Sections 499.012(2)(a) and (c), F.S., unless the department has otherwise made a claim against the bond or security.

(c) A Prescription Drug Wholesaler is authorized to wholesale all prescription drugs, including compressed medical gases and therefore does not require dual permits.

(d) Application requirements for Compressed Medical Gases Wholesalers include:

1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.


3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(e) Application requirements for Prescription Drug Wholesalers, Prescription Drug Wholesalers – Broker Only, or Out-of-State Prescription Drug Wholesalers include:

1. Contact the department’s Drugs, Devices, and Cosmetics Program for an application form(s) and fingerprint cards. Both the sales transaction (seller) and the physical movement (location from which the drugs are shipped) of prescription drugs are considered wholesale distribution. Therefore, if the seller (name and address as reflected on the invoice) is not the same as the location from which the drugs are shipped (name and address), such as in the case of brokers, different branches of the same company, or a contract warehouse, then both persons (the seller and location from which shipped) must be permitted under the Florida Drug and Cosmetic Act.

2. File with the department a completed application for a permit using an original Form DH 2124, “Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application” effective January 2004, which is incorporated by reference herein.

3. File with the department an original Form DH 2125, “Personal Information Statement” effective January 2004, which is incorporated by reference herein for the applicant’s manager, next four highest ranking employees that are
responsible for prescription drug operations, and all affiliated parties.

4. Submit a legible fingerprint card and $47.00 per fingerprint card for each person required to submit a fingerprint card. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

5. Submit a $100,000 bond or security as specified in Sections 499.012(2)(a) and (c), F.S., and paragraph (b) above. If you are using a surety bond, the required bond form is DH 2128, “Surety Bond Form,” effective June 2005, which is incorporated by reference herein.

6. If the applicant is located outside of Florida, submit a photocopy of the resident state’s license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not allow photocopying of the license or permit, the applicant may submit a verification of the license or permit from the issuing agency. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit:
   a. A written confirmation on the letterhead of the resident state agency responsible for regulating prescription drug wholesale distribution in that state that permitting of the applicant establishment is not required by that state; and
   b. A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of 10/1/03) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

7. Identify a person who has been Certified pursuant to Section 499.012(11), F.S., to serve as the certified designated representative. If the prescription drug wholesaler operates in ‘shift’ schedules, a different person per shift may be designated; however the shift hours for which each person is responsible must be clearly identified. You must use Notification of Designated Representative Form DH 2130, effective June 2005, which is incorporated by reference herein, for communicating changes in the designated representative.

8. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

9. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(f) Application requirements for Retail Pharmacy Wholesalers include:
   1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
   3. Submit a photocopy of all permits issued to the applicant’s address which authorize the purchase of prescription drugs at that address, regardless of the issuing agency.
   4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
   5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(g) Application requirements for freight forwarders.
   1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
   3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
   4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(h) Application requirements for Veterinary Prescription Drug Wholesalers include:
   1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
   3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(8) Other Distributors. Persons conducting certain distributions of prescription drugs which are not considered wholesale distributions in the state of Florida must obtain a permit from the department prior to initiating that activity. These permits include Complimentary Drug Distributors, all of the designated Restricted Rx Drug Distributor permits as further discussed in Rule 61N-1.023, F.A.C., Medical Oxygen Retailers, and Veterinary Legend Drug Retailers.

(a) Application requirements for Complimentary Drug Distributors include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program for an application form or download the application from the department’s web site. An out of the state manufacturer or distributor of complimentary or sample prescription drugs may obtain a “Complimentary Drug Distributor permit” for its headquarters or home office in lieu of a permit for each establishment from which complimentary prescription drugs are distributed. A manufacturer or distributor that uses a fulfillment house, shipping and mailing service, or distributes through co-marketing agreements, must notify the department in writing of the contractor’s name, address, and responsibilities prior to the distribution of prescription drug samples in or into this state. The headquarters or home office location is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule and Rule 61N-1.012, F.A.C. A person located within the state that manufactures or distributes complimentary or sample prescription drugs directly or through its agents, employees, or independent contractors, must obtain a Complimentary Drug Distributor permit for each establishment located in Florida. A manufacturer or distributor that uses a fulfillment house, shipping and mailing service, or distributes through co-marketing agreements, any of which is located in Florida, must obtain a permit in the name of the manufacturer or distributor issued to the address of the fulfillment house, shipping and mailing service, or similar location. The manufacturer or distributor is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule and Rule 61N-1.012, F.A.C.
3. Submit a copy of the applicant’s license or permit which authorizes the possession of prescription drugs. If the issuing agency does not allow photocopying of a license or permit, the applicant may submit a verification of the license or permit from the issuing agency.
4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(b) Application requirements for Restricted Rx Drug Distributor – Health Care Entity include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Submit a listing of all the locations under common control that will be receiving distributions under this permit. This listing must include the name and address of the facility and the pharmacy or other permit number which authorizes that location to possess prescription drugs. Additional locations must be communicated to the department in writing prior to the transfer of prescription drugs. Alternatively, depending on the basis for the application, provide a copy of the written contract evidencing the group purchasing organization and a listing of all the locations that will be receiving distributions under this permit because of joint membership in the group purchasing organization.
4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
5. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(c) Application requirements for Restricted Rx Drug Distributor – Charitable Organization include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Submit proof of the charitable organization designation under section 501(c)(3) of the Internal Revenue Code.
4. If the FDA has initiated the enrollment program, submit the FDA central file number of the applicant.
5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
6. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C. 

(d) Application requirements for Restricted Rx Drug Distributor – Reverse Distributor or Restricted Rx Drug Distributor – Destruction include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(e) Application requirements for Restricted Rx Drug Distributor – Government Programs include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Submit a detailed plan justifying the necessity for this permit in accordance with subsection 61N-1.023(5), F.A.C.
4. Submit a list of the intended contractors and subcontractors that will receive the entity’s prescription drugs under this permit and the permit numbers that authorize them to administer or dispense. Also submit a copy of the provisions of the contract that address the requirements in Section 499.012(1)(a)1.d., F.S.
5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
6. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(f) Application requirements for a Restricted Rx Drug Distributor – Institutional Research include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.
4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(g) Application requirements for a Veterinary Legend Drug Retailer include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(h) Application requirements for a Medical Oxygen Retailer include:
1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application or download the application from the department’s web site.
3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.
4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and these rules.
5. Have an FDA establishment registration number if the establishment will be transfilling medical oxygen.

(9) Designated Representative.
   (a) For purposes of the work experience required to be certified as a designated representative:
   1. Serving in a managerial capacity does not require actual supervisory responsibilities over employees, but requires a level of responsibility consistent with a managerial employee, including but not limited to decision-making
authority, responsibility for developing and implementing policies and procedures related to purchasing, sales, or inventory management for prescription drugs.

2. Responsibilities related to recordkeeping for prescription drugs by a person who worked in a pharmacy may include such activities as, practicing pharmacy pursuant to a valid pharmacy license, routinely purchasing or ordering prescription drugs where cognitive functions were involved and the order is not the result of an automated reorder system, routinely receiving prescription drugs and verifying the accuracy of the order, routinely taking a physical inventory of prescription drugs, routinely assessing the pharmacy shelves for outdated prescription drugs, and routinely completing an inventory for the transfer of adulterated prescription drugs for appropriate disposal.

(b) Application requirements for Certification as a Designated Representative include:

1. Contact the department’s Drugs, Devices, and Cosmetics Program to request an application and fingerprint cards or download the application from the program’s web site.

2. File with the department a completed application for certification using Form DH 2126 “Application for Certification as a Designated Representative,” effective June 2005, which is incorporated by reference herein. An application is not deemed completed until the applicant has received a passing score on the laws and rules examination required by Section 499.012(16)(b)4., F.S. The applicant will be notified by regular mail at the applicant’s home mailing address of the applicant’s eligibility to schedule the laws and rules examination. Information on scheduling and other testing processes are included on the program’s web site in a document entitled “Candidate’s Information Booklet.” If the applicant has not passed the laws and rules examination within six months of this notification, the department will initiate action to deny the Application for Certification as a Designated Representative. This six-month period for an applicant to pass the laws and rules examination does not extend the statutory requirement in Section 499.012(16)(f), F.S., for a Prescription Drug Wholesaler Distributor or an out-of-state Prescription Drug Wholesaler Distributor to employ a designated representative.

3. Submit a legible fingerprint card and $47.00 per fingerprint card. The fingerprint card must have been obtained from the department so that the card will have the proper coding for processing and reporting.

4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

5. Comply with all requirements for certification provided in Chapter 499, F.S., and these rules.

(10) Permit renewals for all permits other than a prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler. Submission of a renewal application represents to the department that conditions have not changed with the permitted person which would make the permitted person ineligible to renew the permit.

(a) A permit renewed during the grace period will expire 24 months after the last day of the anniversary month in which the previous permit expired.

(b) An applicant applying to renew a permit which has not expired, been revoked, suspended or otherwise terminated must:

1. File with the department a completed application for a permit using an “Application for Permit Renewal Under Chapter 499, F.S.,” Form DH 1034, effective January 2004, which is incorporated by reference herein. The permittee should contact the department if the renewal application has not been received at least 30 days prior to the permit’s expiration date.

2. Pay the appropriate fee pursuant to this section and Rule 61N-1.018, F.A.C.

3. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

4. Applicants renewing a Retail Pharmacy Wholesaler’s permit must also submit a legible photocopy of the current community pharmacy permit.

(c) If a permit is not renewed prior to the expiration date or within the grace period, the person will be placed out-of-business for purposes of Chapter 499, F.S. In order to be permitted after the expiration of the 60-day grace period, a person must submit a new application and proceed according to the requirements for submission of a new application.

(11) Permit renewals for prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler.

(a) The program will mail an application for renewal of the prescription drug wholesaler, prescription drug
whole. broker only, or out-of-state prescription drug wholesaler permit at least 90 days prior to the expiration date of the permit.

(b) A renewal application that is postmarked within 45 days prior to the expiration date of the permit must include submission of a $100 delinquent fee in addition to the annual permit fee, fingerprint fees, and bond.

(c) File with the department a completed application for a permit using an original Form DH 2124, “Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application” effective January 2004.

(d) File with the department an original Form DH 2125, “Personal Information Statement” effective January 2004, for the applicant’s manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties.

(e) Submit a legible fingerprint card for any person for whom a Personal Information Statement is submitted who has not previously submitted a fingerprint card on behalf of the applicant company. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

(f) Submit $47.00 for each fingerprint card submitted.

(g) Submit a $100,000 bond or security as specified in Sections 499.012(2)(a) and (c), F.S., and paragraph (7)(b) above. If you are using a surety bond, the required bond form is DH 2128, “Surety Bond Form,” effective June 2005.

(h) If the applicant is located outside of Florida, submit a photocopy of the resident state’s current license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not allow photocopying of the license or permit, the applicant may submit a verification of the license or permit from the issuing agency. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit:

1. A written confirmation on the letterhead of the resident state agency responsible for regulating prescription drug wholesale distribution in that state that permitting of the applicant establishment is not required by that state; and
2. A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of 10/1/03) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

(i) Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(j) Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

Rulemaking Authority 499.01, 499.012, 499.0121(1), 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.06, 499.063, 499.064, 499.066, 499.0671 FS. Law Implemented 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.0128(6), 499.04, 499.041, 499.05, 499.06, 499.066, 499.0671 FS. History–New 12-12-82, Amended 7-8-84, 1-30-85, Formerly 10D-45.54, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.054, Amended 1-26-99, 4-17-01, 10-29-02, 7-6-03, 1-1-04, 9-13-04, 10-3-05, 1-19-06, Formerly 64F-12.015.

61N-1.016 Product Registration.

(1) (a) Each drug product shall be registered with the department, but shall not have duplicate registrations. Products that are both a cosmetic and a drug must be registered as a drug.

(b) A formula marketed under different brand names, sizes, quantities, or distributors is not considered a separate and distinct product for registration purposes. Furthermore, the adding of color, flavor, or scents to a formula does not make a separate and distinct product for registration purposes, even for fragrance preparations where the scent is the primary product. However, the different variations must be listed with the department.

(c) The separate and distinct drug product for a person who performs limited manufacturing operations at an establishment such as only encapsulating, sterilizing or other processing or manipulation of the product, but not labeling, may be the product resulting from such processing and not each separate and distinct product to which the limited manufacturing operation is performed.

(d) The application forms incorporated by reference in this rule can be obtained by contacting the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road,
(2)(a) Applicants applying for an initial product registration of a product must:
2. Submit a product label or copy thereof and all labeling associated with the main or identical product that provides information in addition to or other than what is on the product label for every product on the Application (An English translation is required for a product manufactured for export only which has labeling in a foreign language.),
3. Submit documentation that supports the product is allowed to be distributed in interstate commerce as per FDA regulations, such as:
   a. Written documentation from the FDA which indicates approval of a drug through a new drug application – NDA, ANDA, IND, NADA, etc., or
   b. A copy of the section(s) of the Code of Federal Regulations (CFR) denoting the product’s Drug Efficacy Study Implementation (DESI) designation, or
   c. A copy of the section(s) of the CFR denoting the product remains pending final DESI review, or
   d. A copy and summary of material(s) and authoritative literature reviewed during the applicant’s investigation supporting that the product has not yet been reviewed in the DESI process, or
   e. A copy and summary of material(s) and of authoritative literature supporting the product qualifying for grandfather status, or
   f. The over-the-counter monograph category to which the drug belongs, and,
4. Pay the appropriate fee pursuant to Rule 61N-1.018, F.A.C.
(b) Examples of material(s) and authoritative literature used as documentation to meet the requirements of subparagraph (2)(a)3. above, include:
1. Sections of the United States Code (USC) or the CFR,
2. Letters, emails or other forms of communications from the FDA,
3. Evidence that the product is currently being marketed in the United States and that the FDA has actual or constructive knowledge that the product is being marketed in the United States,
4. The Merck Manual of Diagnosis and Therapy,
5. Physicians’ Desk Reference,
6. Remington’s Pharmaceutical Science,
7. Fully cited and copied U.S. medical or pharmaceutical journal articles,
8. DailyMed published by the U.S. National Library of Medicine,
9. Facts and Comparisons, or
10. American Drug Index.
(c) An applicant must amend its product registration list for new products prior to any sales by following the procedures for an initial product registration, listing only those products to be added. Registration for these products will expire concurrently with the biennial cycle for that establishment’s other registered products. Fees will be prorated as provided for in subsection 61N-1.018(4), F.A.C.
(3) Product registration renewal.
(a) Applicants applying for renewal of a product registration must:
2. Submit a product label or copy thereof and all labeling associated with the product if the label or labeling has changed in any respect from the initial or previous renewal registration; and,
3. Pay the appropriate fee pursuant to Rule 61N-1.018, F.A.C.

(b) Registrations issued by the department within the grace period will automatically expire 24 months after the last day of the month in which the previous registration expired.

Rulemaking Authority 499.05, 499.012 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.05, 559.79(2) FS. History—New 7-1-96, Formerly 10D-45.0542, Amended 1-26-99, 4-17-01, 1-1-04, Formerly 64F-12.016, Amended 8-2-15, 11-2-17.

61N-1.017 Certificates of Free Sale.

(1) A written request for a certificate of free sale must be submitted to the department by the Florida permitted manufacturer of the drug indicating the name and address of the company to be designated on the free sale certificate as the distributor or manufacturer or both; the name, address, and product registration number of the company who has registered the product; the specific name of the product(s) to be included in the certificate; the product label if a current label is not on file with the department; and the appropriate fee as provided in Rule 61N-1.018, F.A.C.

(2) A maximum of 30 product names can be included on one certificate of free sale.

Rulemaking Authority 499.05, 499.015 FS. Law Implemented 499.015, 499.04, 499.05 FS. History—New 7-1-96, Formerly 10D-45.0543, Amended 4-17-01, Formerly 64F-12.017, Amended 10-24-17.

61N-1.018 Fees.

(1) Biennial fees for a Manufacturer or Repackager permit are as follows:

<table>
<thead>
<tr>
<th>Permit Type</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Drug Manufacturer (including virtual)</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Prescription Drug Repackager</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Device Manufacturer</td>
<td>$1,200.00</td>
</tr>
<tr>
<td>Cosmetic Manufacturer</td>
<td>$800.00</td>
</tr>
<tr>
<td>Over-the Counter Drug Manufacturer</td>
<td>$800.00</td>
</tr>
<tr>
<td>Medical Gas Manufacturer</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Non-resident Prescription Drug Manufacturer</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Non-resident Prescription Drug Repackager</td>
<td>$1,500.00</td>
</tr>
</tbody>
</table>

No manufacturer shall be required to pay more than one fee per establishment to obtain an additional manufacturing permit; but the manufacturer must pay the highest fee applicable to the operations in each establishment.

(2)(a) Biennial fees for a Wholesale Distributor or Freight Forwarder permit that is issued on a Biennial basis are as follows:

<table>
<thead>
<tr>
<th>Permit Type</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Gas Wholesale Distributor</td>
<td>$600.00</td>
</tr>
<tr>
<td>Retail Pharmacy Drug Wholesale Distributor</td>
<td>$100.00</td>
</tr>
<tr>
<td>Freight Forwarder</td>
<td>$600.00</td>
</tr>
<tr>
<td>Veterinary Prescription Drug Wholesale Distributor</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Limited Prescription Drug Veterinary Wholesale Distributor</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Prescription Drug Wholesale Distributor (including Broker Only)</td>
<td>$1,600.00</td>
</tr>
<tr>
<td>Out-of-State Prescription Drug Wholesale Distributor</td>
<td>$1,600.00</td>
</tr>
</tbody>
</table>

(3) Biennial fees for Other permits are as follows:

<table>
<thead>
<tr>
<th>Permit Type</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complimentary Drug Distributor</td>
<td>$500.00</td>
</tr>
<tr>
<td>Veterinary Prescription Drug Retail Establishment</td>
<td>$600.00</td>
</tr>
</tbody>
</table>
Medical Oxygen Retail Establishment
Restricted Prescription Drug Distributor – Blood Establishment
Restricted Prescription Drug Distributor – Health Care Entity
Restricted Prescription Drug Distributor – Charitable Organization
Restricted Prescription Drug Distributor – Reverse Distributor
Restricted Prescription Drug Distributor – Destruction
Restricted Prescription Drug Distributor – Government Programs
Restricted Prescription Drug Distributor – Institutional Research
Third Party Logistics Provider
Health Care Clinic Establishment

(4) Miscellaneous Other fees are as follows:

   Fee

(a) Certification as Designated Representative $150.00
(b) Initial Application/Onsite Inspection $150.00 Non-Refundable

The initial application/onsite inspection fee is non-refundable.

If the department determines it must re-inspect for an initial application because the applicant does not have security, climate control, a quarantine area, or written policies and procedures, as required by the particular permit for which the applicant is applying; fails to appear for a scheduled inspection; or is otherwise not ready or available for inspection or available to schedule an inspection on or after the date indicated on the application form, an additional onsite inspection fee of $150.00 is required for each reinspection.

(c) Bond/Security: Prescription Drug Wholesale Distributor or Out-of-State Prescription Drug Wholesale Distributor with more than $10,000,000.00 million in annual gross receipts during the previous tax year, as set forth in Section 499.012(8)(m), F.S.

(d) Bond/Security: Prescription Drug Wholesale Distributor or Out-of-State Prescription Drug Wholesale Distributor with $10,000,000.00 million or less in annual gross receipts during the previous tax year, as set forth in Section 499.012(8)(m), F.S.

(e) Bond/Security: Limited Prescription Drug Veterinary Wholesale, as set forth in Section 499.01(2)(m), F.S.

(f) Change of Address:

A relocation fee of $100.00 must be paid for each permitted person or establishment relocating for which an onsite inspection is required. If no onsite inspection is required, the relocation fee is $25.00 per permit. If a permitted person has multiple permits under the same permitted name and address and relocates any or all permitted activities concurrently to the new location, then only one $100.00 fee is required plus $25.00 for each additional permit.

(g) Product Registration (for each drug product registered) $30.00*

*The registration fee for a prescription drug product being amended to an existing product registration that has 12 months or less until it expires is $15.00.

(h) Listed Identical Products $15.00

(i) Free Sale Certificate $25.00

Signature of Free Sale Certificate copy (requested concurrently) $2.00

(j) Delinquent Establishment Permit Renewal (per permit) $100.00

Rulemaking Authority 499.01, 499.04, 499.05, 499.831, 499.832 FS. Law Implemented 499.01, 499.012, 499.014, 499.041, 499.05, 499.028, 499.831, 499.832 FS. History–New 7-1-96, Formerly 10D-45.0544, Amended 4-17-01, 7-6-03, 1-1-04, 9-13-04, 2-14-06, 9-5-07, 3-10-09, Formerly 64F-12.018, Amended 6-3-15, 11-2-17.
61N-1.019 Inspections, Investigations, Monitoring.

(1) An inspection or investigation is a review or examination of an establishment permitted under the provisions of Chapter 499, F.S., or any rule adopted thereunder, or of a non-permitted establishment for the purpose of protecting public health from misbranded or adulterated drugs, devices, or cosmetics or from any other violation of Chapters 499 and 893, F.S., or any rules adopted thereunder. An inspection may also take place in a non-permitted establishment to assess whether the establishment complies with the requirements for a Chapter 499, F.S., permit.

(2) The department may inspect, monitor, and investigate all drug, device and cosmetic manufacturers, wholesalers, repackers, distributors, or other establishments where drugs, devices or cosmetics are made, stored, sold, offered for sale, exposed for sale, or kept for sale or use, for the purpose of determining compliance with the provisions of Chapters 499 and 893, F.S., or any rules adopted thereunder and to secure evidence of any non-compliance.

(3) Inspections and investigations may be announced or unannounced, at the discretion of the department. The owner, officer, or employee of the establishment shall make the premises and all records and other information required by Chapters 499 and 893, F.S., or any rules adopted thereunder available to the department inspector.

(4) Inspections and investigations under this rule may include:
   (a) Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any prescription, over-the-counter or investigational drug, device or cosmetic. These records include, but are not limited to receiving documents, shipping documents, purchase orders, purchase requisitions, invoices, paid receipts, contracts, checks, deposits, and credits or debits in any form whatsoever;
   (b) Entry to any establishment, vehicle or space therein in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;
   (c) Entry to any establishment, vehicle, or space therein in which records related to drugs, devices, or cosmetics are held;
   (d) Surveillance of procedures related to drugs, devices or cosmetics;
   (e) Collection of facts and information related to drugs, devices or cosmetics;
   (f) Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to drugs, devices or cosmetics;
   (g) Sampling any drug, device or cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;
   (h) Photographing any drug, device or cosmetic including any related component, materials, physical plant, storage condition, article or product;
   (i) Observations and identification of:
      1. Any drug, device or cosmetic consisting wholly or in part of filthy, putrid or decomposed substances,
      2. Any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a drug, device or cosmetic becoming adulterated or misbranded,
      3. Any unsanitary conditions or practices which may render a drug, device or cosmetic injurious to health,
      4. Any faulty manufacturing, processing, packaging, or holding of drugs, devices or cosmetics as related to current good manufacturing practices (CGMP) including recordkeeping,
      5. Any deviation from recommended processing, storage or temperature requirements for any drug, device or cosmetic as specified by federal or state law,
      6. Any deviation from FDA requirements for the label and labeling of any drug, device or cosmetic,
      7. Any other action to determine compliance with Chapters 499 and 893, F.S., and this rule chapter.
   (j) Taking of evidence related to a drug, device or cosmetic that is or may be in violation of Chapter 499 or 893, F.S., or any rules adopted thereunder; and,
   (k) Securing the removal of any potentially misbranded or adulterated drug, device, or cosmetic from commerce or public access.

(5) The department shall take reasonable steps to assure that a sampled product is not reintroduced into commerce if it is or has become adulterated or misbranded.

Rulemaking Authority 499.05, FS. Law Implemented Chapter 499, Parts I and II, FS. History-New 7-8-84, Formerly 10D-45.545, Amended 11-26-86, 7-1-96, Formerly 10D-45.0545, Amended 4-17-01, Formerly 64F-12.019.
61N-1.020 Forms.

Rulemaking Authority 499.01, 499.012, 499.0122, 499.013, 499.015, 499.018, 499.028, 499.04, 499.041, 499.05, 499.06, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS. Law Implemented 499.01, 499.012, 499.0122, 499.013, 499.015, 499.018, 499.028, 499.04, 499.041, 499.05, 499.06, 499.062, 499.063, 499.064, 499.066, 499.067 FS. History–New 12-12-82, Formerly 10D-45.56, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.056, Amended 1-26-99, 1-1-04, Formerly 64F-12.020, Repealed 6-30-15.

61N-1.021 Trade Secrets.

(1) A person must indicate in writing at the time information is submitted to the department that the information includes material which is a trade secret as defined by Section 812.081(1)(c), F.S., or other confidential material exempt from the provisions of Chapter 119, F.S., the basis for the claim of trade secret and that the person does not wish this trade secret to be made public.

(2) Trade secret information must be specifically identified and noted on the documents submitted to the department.

(3) In the event the department seizes information pursuant to its inspectional authority under Section 499.051, F.S., or Rule 61N-1.019, F.A.C., the person from whom the information is seized will be granted an opportunity to claim and designate trade secret information in accordance with this rule prior to the department completing enforcement action.

Rulemaking Authority 499.05 FS. Law Implemented 381.83, 499.051(5) FS. History–New 12-12-82, Formerly 10D-45.57, Amended 7-1-96, Formerly 10D-45.057, 64F-12.021.

61N-1.022 Ether Applications; Licensing; Permitting; Records; Security; Distributing; Disposal.

(1) Any person requiring a license or permit may request an Application for Diethyl Ether Permit DOH Form 1672, ed. Aug. 94, which is incorporated by reference herein. To renew a permit which has not expired, been revoked, suspended or otherwise terminated, a person must file with the department a completed “Application for Diethyl Ether Permit Renewal Under Chapter 499, F.S.,” DOH Form 1034E, effective January 1996, which is incorporated by reference herein.

(a) The following items must accompany the initial Application for Diethyl Ether Permit and renewal applications:

1. Accurate and Current Photographs – Two accurate and current photographs, taken within 6 months of the submission date of the application, of the chief executive officer or owner. The photographs must measure 2 inches by 2 inches and be clearly recognizable with a front view, full face image.

2. Fingerprint Cards – A complete set of fingerprints of the applicant taken by an authorized law enforcement officer on forms provided by the department. A new set of fingerprint cards is not required if the applicant is applying for a renewal license or permit for a license or permit held during the prior license or permit year which was not suspended or revoked and the chief executive officer has not changed.

(b) The following fees are payable to the Florida Drug, Device, and Cosmetic Trust Fund and must be submitted with an initial application or renewal application for a license or permit to handle diethyl ether:

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>$700.00</td>
</tr>
<tr>
<td>Distributor</td>
<td>$700.00</td>
</tr>
<tr>
<td>Dealer</td>
<td>$350.00</td>
</tr>
<tr>
<td>Purchaser</td>
<td>$150.00</td>
</tr>
</tbody>
</table>

(2) A person who uses ether for lawful research, teaching, or testing may obtain an exemption letter from the department to authorize acquisition of ether for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the person who will be responsible for the ether, that the ether will be secured, that access will be restricted to authorized persons, and that the ether is not for resale. This correspondence should also identify the name in which purchases will be made, the quantity which will be purchased, the frequency of the purchases, and the name and Florida license number of the supplier of the ether. The department may waive any or all of these specific elements...
due to the nature of the research, teaching or testing, and the department may require additional information, such as photographs and fingerprint verification, as a condition of issuing the exemption letter. The department may issue an exemption letter to the person which authorizes the purchase or other acquisition and possession of ether. A copy of this exemption letter must be included with required record documentation.

(3) Records:
(a) All persons who are exempt from licensure and reside in the state of Florida shall keep records of ether purchases, use, or disposition which shall be made immediately available to authorized agents of the department of the Department of Law Enforcement.
(b) All original invoices or other documentation representing the sale or transfer of ether required by Part III of Chapter 499, F.S., shall include the name, address and license or permit number of the seller/transferor; the name, address and license or permit number of the recipient/transferee; the date of transfer; and the signature of the purchaser. A copy of an exemption letter issued by the department as provided in subsection (2), of this rule, must be maintained for all sales of ether in excess of 2.5 gallons to persons who are exempt from licensure. All required records shall be retained for a period of 5 years and shall be immediately available and subject to examination and copying by the department and the Florida Department of Law Enforcement of each such transaction.
(c) Computer Records – Records of each transaction involving ether may be maintained by electronic methods, such as computers or imaging devices. The original invoices and other records bearing the information required, or true copies of these original records, must be maintained by the person involved in the transaction, including each broker and agent.

(4) Security: Every person in the state who possesses ether shall secure it in a manner which functionally and practically deters unauthorized access to the ether.

Rulemaking Authority 499.701 FS. Law Implemented Part III of Chapter 499 FS. History–New 11-26-86, Formerly 10D-45.58, Amended 2-4-93, 7-1-96, Formerly 10D-45.058, 64F-12.022.

61N-1.023 Restricted Prescription Drug Distributor Permits; Special Provisions.
The following Restricted Prescription (Rx) Drug Distributor permits will be issued by the department:
(1) Restricted Rx Drug Distributor – Charitable Organization. This permit is required for a charitable organization to authorize the possession or transfer of prescription drugs, including prescription drug samples. A charitable institution which is otherwise licensed to use, administer, or dispense prescription drugs and which does not distribute or transfer prescription drugs is not required to obtain this permit.
(a) Transfers authorized by this permit are limited to nonprofit affiliates of the permittee authorized to possess prescription drugs, exports to charitable organizations in other countries in compliance with applicable federal and state exportation laws, and the daily transfer to a Florida licensed practitioner authorized to administer or dispense for the purpose of administering or dispensing the prescription drug to patients of the charitable organization with the daily return by the practitioner to the charitable organization permittee of the unused prescription drugs.
(b) Each Restricted Rx Drug Distributor – Charitable Organization permittee shall comply with the following procedures for soliciting and receiving donated prescription drugs, including samples:
1. An identification document shall be provided to any employee or agent authorized to act on behalf of the permittee in soliciting or receiving donations of prescription drugs. The identification document must be in a form which prevents alteration and shall be valid for a limited term. At a minimum it must identify the expiration date; the name, address, FDA central file number, if adopted by the FDA, and state license or permit number of the charitable organization; exhibit the name, signature, and photograph of the authorized employee or agent; and an affirmative statement that the person identified on the document is authorized by the institution to solicit and receive donations of prescription drugs on behalf of the permittee. Upon termination of these responsibilities by the employee or agent or expiration of the identification document, the document must be returned to the permittee for destruction.
2. Maintain a current listing of all employees or agents authorized to solicit and receive prescription drugs on behalf of the permittee.
3. A permittee may only receive a donated prescription drug in its original, unopened packaging with its labeling intact.
(c) The charitable organization may transfer prescription drugs on a daily basis to a Florida licensed medical practitioner providing services to patients of the charitable organization on behalf of the charitable organization. If the practitioner leaves the charitable organization establishment with prescription drugs of the charitable organization, a record documenting the daily transfer to the practitioner must be prepared as well as a record of the prescription drugs administered or dispensed and the prescription drugs returned by the practitioner to the charitable organization upon completion of providing services for the charitable organization on that date.

(2) Restricted Rx Drug Distributor – Health Care Entity. This permit is required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in Section 499.012(1)(a), F.S.; or (2) members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under “common control” as defined in Section 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. This permit also authorizes a warehouse or purchasing depot of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with Section 240.241, F.S. All requirements of paragraph (6), of this rule, related to the Restricted Rx Drug Distributor – Institutional Research permit must be complied with for transfers under this provision.

(3) Restricted Rx Drug Distributor – Reverse Distributor. This permit is required for persons engaged in the handling, processing and removal of expired or otherwise adulterated or unsuitable prescription drugs on behalf of licensed pharmacies, practitioners, wholesalers, or other persons authorized to possess prescription drugs, hereafter referred to as the “owner establishment” for return to the manufacturer or source of the prescription drug or for destruction. This permit authorizes the reverse distribution of prescription drugs removed from the owner establishment to the manufacturer or source or to a person authorized to arrange for destruction of prescription drugs. This permit is not required if a person only performs the service of processing prescription drugs (preparing the inventory) for return or destruction and does not physically remove any prescription drugs from the owner establishment. A Restricted Rx Drug Distributor – Reverse Distributor permit cannot be issued to the same address or to an address adjacent to a prescription drug wholesaler or prescription drug manufacturer.

(a) As a part of the audit trail and documentation required by Rule 61N-1.012, F.A.C., records must identify at a minimum the name of the prescription drug product and whether it is a prescription drug sample, the manufacturer, and the quantity for each prescription drug removed from the establishment. The NDC code may be used to identify the manufacturer. For partially filled containers, the quantity at a minimum must be estimated.

(b) If the reverse distributor sends prescription drugs to any establishment other than to the manufacturer, that establishment must be authorized to receive adulterated prescription drugs for reverse distribution or destruction purposes. Once a prescription drug has been accepted by a reverse distributor for processing, it cannot be returned to the owner establishment without the written approval of the department.

(c) If a reverse distributor also arranges for the destruction of prescription drugs, dual permitting as a Restricted Rx Drug Distributor – Destruction is not required; however, the reverse distributor must follow all requirements of the Restricted Rx Drug Distributor – Destruction permittee prescribed by subsection (4), of this rule.

(d) In addition to the requirements included here, Controlled Substances must be handled in accordance with D.E.A. provisions. If any conflict exists between D.E.A. provisions and those enumerated herein, the D.E.A. provisions must be followed.

(4) Restricted Rx Drug Distributor – Destruction. This permit is required for a person to take possession in Florida of a prescription drug for the purpose of arranging for its destruction; other than the manufacturer of that drug or a permitted Restricted Rx Drug Distributor – Reverse Distributor. This includes persons transporting prescription drugs to a destruction facility or to a warehouse awaiting destruction, and persons warehousing prescription drugs prior to destruction. Common carriers are not required to obtain this permit, however, contract or private carriers must obtain this permit prior to obtaining possession of the prescription drugs in Florida. A destruction facility (such as a landfill or incineration facility) is not required to obtain this permit if the prescription drugs are destroyed immediately upon receipt. This permit is not required if a person only performs the service of processing
A Restricted Rx Drug Distributor – Destruction permit cannot be issued to the same address or to an address adjacent to a prescription drug wholesaler or prescription drug manufacturer.

(a) A Restricted Rx Drug Distributor – Destruction permittee that warehouses or stores prescription drugs prior to destruction must meet the security requirements of a prescription drug wholesaler as enumerated in Section 499.0121(1)(b), F.S., and subsections 61N-1.013(1) and (2), F.A.C., but is not required to meet temperature storage requirements.

(b) As a part of the audit trail and documentation required by Rule 61N-1.012, F.A.C., records, must identify, at a minimum, the name of the product to be destroyed and whether it is a prescription drug sample, the manufacturer, and the quantity for each prescription drug to be destroyed. The NDC code may be used to identify the manufacturer. For partially filled containers, the quantity, at a minimum, must be estimated. Records are required for each transfer of prescription drugs until the drugs have been destroyed.

(c) A Certificate of Destruction must be received from the facility responsible for the ultimate destruction or incineration of the prescription drugs. This certificate shall provide the weight of the prescription drugs destroyed, the manner of destruction, and the time, date and location of the destruction. The Certificate of Destruction must be attached to the records containing the elements set forth in paragraph (4)(b), which details the prescription drugs destroyed.

(d) In addition to the requirements included here, Controlled Substances must be handled in accordance with D.E.A. provisions. If any conflict exists between D.E.A. provisions and those enumerated herein, the D.E.A. provisions must be followed.

(e) In addition to the requirements included here, transporting, storage, and destruction of prescription drugs are also regulated by federal, state and local environmental agencies.

(5) Restricted Rx Drug Distributor – Government Programs. This permit is required for a state or local government agency, or any entity eligible to purchase prescription drugs at public health services prices pursuant to section 602, PL 102-585, hereafter “the entity,” to distribute its prescription drugs to a contract provider or its subcontractor for administering or dispensing to eligible patients of the entity under the eligible program. A prescription drug distributed under this permit may not be sold or transferred for reimbursement or payment of any kind.

(a) The applicant must submit to the department a detailed plan justifying the necessity for this permit which demonstrates that the transfer of a prescription drug under this subsection will enhance the public’s health by improving access, quality, or safety because current drug delivery systems to reach patients of the entity are inadequate. The department will issue the Restricted Rx Drug Distributor – Government Programs permit if the intended distribution enhances accessibility, quality, or safety as set forth in the previous sentence for patients in Florida and does not endanger public health, safety and welfare. To assess the ongoing need for an entity to hold a Restricted Rx Drug Distributor – Government Programs permit, the bureau will periodically request information from the permit holder regarding continued justification under this subsection and may specifically consider inadequate accountability or monitoring as endangering public health, safety and welfare.

(b) The entity must monitor the prescription drugs transferred under this permit. Discrepancies must be investigated and reported by the entity to the bureau.

(6) Restricted Rx Drug Distributor – Institutional Research. This permit is required for a licensed pharmacy of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with Section 240.241, F.S.

(a) A non-practitioner recipient researcher is not required to obtain an exemption letter pursuant to subsection 61N-1.011(4), F.A.C., if the researcher and research activities are located on the university campus. However, if the researcher is not located on the university campus and the drug is not stored on the university campus, then an exemption letter is required prior to the transfer of any prescription drugs to the researcher.

(b) The Restricted Rx Drug Distributor – Institutional Research permit holder must maintain records that include at a minimum, the researcher; specific research project/grant number; location in which the research is done and/or storage location of the prescription drug and the researcher’s exemption number if applicable; and the name, strength, dosage form, and quantity of the drug transferred to the researcher. The researcher’s DEA number is also
required if a controlled substance has been transferred to the researcher. The researcher must sign for the prescription drug with an acknowledgement that the drug cannot be sold, traded or transferred to anyone not directly involved in the specific research project for which the drug was obtained. If the permit holder is a pharmacy, these records must be maintained separate from the pharmacy dispensing records.

c) The recipient researcher must maintain security over any prescription drugs and adequate recordkeeping to account for disposition of all prescription drugs received.

d) The university must designate an individual responsible for periodic monitoring of the distributions under this permit. Such monitoring must include, but is not limited to, unannounced inspections and reconciliation of the inventory of prescription drugs in the researcher’s possession and records of prescription drugs used by university researchers. Discrepancies must be investigated and corrective action implemented as indicated.

Rulemaking Authority 499.014, 499.05 FS. Law Implemented 499.01, 499.012, 499.0121, 499.014 FS. History –New 7-1-96, Formerly 10D-45.059, Amended 1-26-99, 4-17-01, Formerly 64F-12.023.

61N-1.024 Administrative Enforcement.

(1) In addition to any other action authorized by law, the department will issue a notice of violation, warning letter, or notice of inspection results to any person that violates Chapter 499, Part I, F.S., and this rule chapter if the documented facts of the case so warrant.

(2) The department sets forth below a summary listing of prohibited acts or other actions which constitute a violation of Chapter 499, F.S., or the rules adopted thereunder. The purpose of this listing is to give notice to permittees, registrants and other persons of the range of penalties which will normally be imposed for violation of particular provisions of Chapter 499, F.S., or rules adopted thereunder in a case where a person is adjudged by the department by final order incorporating an Administrative Complaint to have violated a provision of Chapter 499, F.S., or Chapter 61N-1, F.A.C. Whenever a violation of a particular provision of Chapter 499, F.S., or Chapter 61N-1, F.A.C., is addressed by more than one guideline penalty provision below, the more severe applicable penalty provision will apply. The descriptions of the violations below are only intended to be generally descriptive. The reader should look to the actual statutory and rule provisions cited below to determine the conduct the law actually requires or prohibits.

(3) The guidelines are based upon a single count violation of each provision listed. Each separate violation of a provision of Chapter 499, F.S., or Chapter 61N-1, F.A.C., is subject to a separate fine. Each day a violation continues constitutes a separate violation.

(4) These guidelines generally reflect the Department’s position as to the severity of a given violation. In determining the applicable penalty within a given guideline range, for a violation of a provision of Chapter 499, Part I, F.S., or a rule adopted thereunder, the Department will also consider any previous violations of those provisions by a person as well as any actions taken to correct a violation or remedy complaints.

(5) The following codes outline department policy under Section 499.066, F.S., and are used to designate the general severity in terms of the threat to the public health for a violation.

<table>
<thead>
<tr>
<th>Violation</th>
<th>General Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 = Administrative Complaint with a fine ranging from $250.00 to $1,000.00 per violation and up to suspension of permits for one year.</td>
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<tr>
<td>2 = Administrative Complaint with a fine ranging from $1,000.00 to $3,000.00 per violation, and up to permanent suspension or revocation of permits.</td>
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</tr>
<tr>
<td>1 = Administrative Complaint with a fine ranging from $3,000.00 to $5,000.00 per violation; and up to permanent suspension or revocation of permits.</td>
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</tr>
</tbody>
</table>

CITE 499 refers to Chapter 499, F.S.
1 refers to Chapter 61N-1, F.A.C.
FACILITY, STORAGE: Section 499.0121(a), F.S.;
<table>
<thead>
<tr>
<th>Section/Subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsection 61N-1.014(4), F.A.C.</td>
<td>Inadequate facility.</td>
</tr>
<tr>
<td>Section 499.0121(1)(b), F.S.</td>
<td>Inadequate security.</td>
</tr>
<tr>
<td>Section 499.0121(1)(a), F.S.</td>
<td>Unrestricted access to prescription drugs.</td>
</tr>
<tr>
<td>Subsection 61N-1.022(4), F.A.C.</td>
<td>Unrestricted access to ether.</td>
</tr>
<tr>
<td>Section 499.0121(3), F.S.</td>
<td>Inadequate storage.</td>
</tr>
<tr>
<td>Subsections 61N-1.013(3), and 61N-1.014(1), F.A.C.</td>
<td>Improper temperature conditions.</td>
</tr>
<tr>
<td>Section 499.0121(1)(b), F.S.</td>
<td>Improper ventilation/physical access.</td>
</tr>
<tr>
<td>Section 499.0121(1)(c), F.S.; subsection 61N-1.013(4), F.A.C., and Section 499.05355(2), F.S.</td>
<td>No quarantine area.</td>
</tr>
<tr>
<td>Section 499.012(6), F.S.</td>
<td>Failure to comply with Section 499.012(6), F.S.</td>
</tr>
<tr>
<td>Section 499.005(4), F.S.</td>
<td>Activity in violation of law or rules.</td>
</tr>
<tr>
<td>Section 499.005(20), F.S.</td>
<td>Import prescription drug contrary to Federal Food Drug and Cosmetic Act.</td>
</tr>
<tr>
<td>Section 499.005(21), F.S.</td>
<td>Wholesaling health care entity Rx drugs.</td>
</tr>
<tr>
<td>Sections 499.01(2)(j), and (2)(m), F.S.</td>
<td>Returning sold drug to inventory.</td>
</tr>
<tr>
<td>Subsection 61N-1.023(5), F.A.C.</td>
<td>Failure to monitor.</td>
</tr>
<tr>
<td>Section 499.005(7), F.S.</td>
<td>Using currency for Rx drug transaction.</td>
</tr>
<tr>
<td>OPERATING: Sections 499.005(6), and 499.67(5), F.S.</td>
<td>Refusing entry, inspection, taking evidence.</td>
</tr>
<tr>
<td>Paragraph 61N-1.015(2)(c), F.A.C.</td>
<td>Inaccessible during business hours.</td>
</tr>
<tr>
<td>Sections 499.005(22), 499.62, F.S., and Rule 61N-12.015, F.A.C.</td>
<td>Failure to obtain proper permit.</td>
</tr>
<tr>
<td>Section 499.015, F.S., and Rule 61N-12.016, F.A.C.</td>
<td>Failure to register products ($50 per product per year).</td>
</tr>
<tr>
<td>Section 499.01(4)(a), F.S., and 61N-12.016(4), F.A.C.</td>
<td>Failure to notify dept. of address change.</td>
</tr>
<tr>
<td>Section 499.012(16), F.S.</td>
<td>Violation by or related to certified representative.</td>
</tr>
<tr>
<td>Section 499.039, F.S.</td>
<td>Transfer of harmful substance.</td>
</tr>
<tr>
<td>Section 499.039, F.S.</td>
<td>Transfer violation causing injury.</td>
</tr>
<tr>
<td>RECORDKEEPING: Sections 499.005(18), 499.0121(6), 499.028, 499.052, 499.66, 499.67, F.S., and Rule 61N-1.012, subsection 61N-1.022(3), F.A.C.</td>
<td>Failing to maintain records, inventories.</td>
</tr>
<tr>
<td>Sections 499.66, 499.67, F.S., and Rule 61N-1.012, F.A.C.</td>
<td>Failing to make records available.</td>
</tr>
<tr>
<td>Section 499.005(28), F.S.</td>
<td>Absence of/not providing pedigree papers.</td>
</tr>
<tr>
<td>Subsection 61N-1.012(1), F.A.C.</td>
<td>Not maintaining a complete audit trail.</td>
</tr>
<tr>
<td>Subsection 61N-1.012(12), F.A.C.</td>
<td>Separate records, multiple businesses.</td>
</tr>
<tr>
<td>Subsection 61N-1.007(2), F.A.C.</td>
<td>No written procedures for medical oxygen.</td>
</tr>
<tr>
<td>SAMPLES: Section 499.005(17), F.S.</td>
<td>Sample drug distribution – activity with.</td>
</tr>
<tr>
<td>Section 499.005(25), F.S.</td>
<td>Charging a dispensing fee for a prescription sample.</td>
</tr>
<tr>
<td>ADULTERATED AND MISBRANDED:</td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>499.005(1), F.S.</td>
<td>Activity with adulterated or misbranded product.</td>
</tr>
<tr>
<td>499.005(2), F.S.</td>
<td>Adulterating or misbranding a product.</td>
</tr>
<tr>
<td>499.005(3), F.S.</td>
<td>Receiving adulterated/misbranded product.</td>
</tr>
<tr>
<td>499.005(9), F.S.</td>
<td>Making a product misbranded.</td>
</tr>
<tr>
<td>499.013(2)(a), F.S.</td>
<td>Prescription Drug Manufacturer not following GMP.</td>
</tr>
<tr>
<td>499.013(2)(b), F.S.</td>
<td>OTC Drug Manufacturer not following GMP.</td>
</tr>
<tr>
<td>499.013(2)(c), F.S., and subsection 61N-1.007(1), F.A.C.</td>
<td>Comp. Med. Gas Manufacturer not following GMP.</td>
</tr>
<tr>
<td>499.013(2)(d), F.S.</td>
<td>Device Manufacturer not following GMP.</td>
</tr>
<tr>
<td>Rule 61N-1.010, F.A.C.</td>
<td>Cosmetic Manufacturer not following GMP/guidelines.</td>
</tr>
<tr>
<td>499.005(1), F.S.</td>
<td>Activity with drug which left regulatory control, GMP.</td>
</tr>
<tr>
<td>499.005(26), F.S.</td>
<td>Removing pharmacy dispensing label.</td>
</tr>
<tr>
<td>499.005(27), F.S.</td>
<td>Distributing previously dispensed Rx drug.</td>
</tr>
<tr>
<td>Sections 499.005(28), and (29), F.S.</td>
<td>Pedigree paper violation.</td>
</tr>
<tr>
<td>499.0121(4)(d), F.S.</td>
<td>Failure to authenticate pedigree.</td>
</tr>
<tr>
<td>Section 499.005(8), F.S.</td>
<td>Making/dealing in a counterfeit product.</td>
</tr>
<tr>
<td>Section 499.005(5), F.S., and Rule 61N-1.002, F.A.C.</td>
<td>Disseminating false/misleading ad.</td>
</tr>
<tr>
<td>499.005(10), F.S.</td>
<td>Forging, counterfeiting, falsely representing a product.</td>
</tr>
<tr>
<td>499.005(11), F.S.</td>
<td>Labeling or advertisement of effectiveness when not.</td>
</tr>
<tr>
<td>Sections 499.005(19), 499.005(23), 499.66 and 499.67, F.S.</td>
<td>Making false or fraudulent statements.</td>
</tr>
<tr>
<td>Section 499.005(19), 499.64(4), and 499.67, F.S.</td>
<td>Providing department with false/fraudulent records/statements.</td>
</tr>
<tr>
<td>Section 499.005(13), F.S.</td>
<td>Activity w/self-testing HIV/AIDS products.</td>
</tr>
<tr>
<td>Section 499.005(14), F.S.</td>
<td>Purchase or receipt of prescription drug from unauthorized source.</td>
</tr>
<tr>
<td>Section 499.005(16), F.S.</td>
<td>Purchase or receipt of Comp. Med. Gas from unauthorized source.</td>
</tr>
<tr>
<td>Section 499.005(15), F.S.</td>
<td>Sale or transfer of prescription drug to unauthorized person.</td>
</tr>
<tr>
<td>Section 499.005(24), F.S.</td>
<td>Sale or transfer of legend device to unauthorized person.</td>
</tr>
<tr>
<td>499.01(2)(j), F.S. and subsection 61N-1.012(4), F.A.C.</td>
<td>Improper sale of veterinary Rx drug.</td>
</tr>
<tr>
<td>Subsection 61N-1.012(4), F.A.C.</td>
<td>Distribution of medical oxygen by medical oxygen retailer without a prescription (order)</td>
</tr>
<tr>
<td>Section 499.66, F.S.</td>
<td>Sale or transfer of ether to unauthorized person.</td>
</tr>
<tr>
<td>Section 499.01(2)(j), F.S.</td>
<td>Activity relating to human Rx drug by Vet. Retailer.</td>
</tr>
<tr>
<td>Section 499.01(2)(p1.), F.S.</td>
<td>Possession of prescription drug by OTC Mfgr.</td>
</tr>
<tr>
<td>Section 499.01(2)(o1.), F.S.</td>
<td>Possession or manufacture of other Rx drug by Comp. Med. Gas Manufacturer.</td>
</tr>
<tr>
<td>Section 499.01(2)(m), F.S.</td>
<td>Possession of other Rx drugs by medical oxygen retailer.</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>499.023, F.S.</td>
<td>Activity with unapproved new drug.</td>
</tr>
<tr>
<td>499.03(1), F.S.</td>
<td>Illegal possession, etc. of habit forming toxic, etc. new drug.</td>
</tr>
<tr>
<td>499.005(12), F.S.</td>
<td>Possession in violation of Sections 499.001-499.081, F.S.</td>
</tr>
<tr>
<td>499.028(15), F.S.</td>
<td>Illegal possession of a sample drug.</td>
</tr>
<tr>
<td>499.65, F.S.</td>
<td>Illegal possession of ether &gt;2.5 gallons.</td>
</tr>
<tr>
<td>499.69, F.S.</td>
<td>Possession of ether within 500' of residence.</td>
</tr>
</tbody>
</table>

(6) Administrative fines due the department may be paid by personal check, corporate check, cashier’s check, certified check, money order, or other guaranteed funds, payable to the Department of Business and Professional Regulation, Drugs, Devices and Cosmetics Program, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047. The department will take further legal action, including but not limited to, enforcing the underlying agreement if payment of an administrative fine by means of non-guaranteed funds does not result in the full payment of the fine.

(7) If a limited prescription drug veterinary wholesale distributor, prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor fails to pay an administrative fine or costs within 30 days after the fine or costs become final, the department may make a claim against the bond or other security as authorized by Chapter 499, F.S., and this rule chapter.

(8) For any alleged violation of Chapter 499, F.S., or Chapter 61N-1, F.A.C., the Department may elect to provide the alleged violator with a notice of violation, in order to facilitate the uncontested settlement of all issues related to a complaint or investigation. Generally, this will be done at the completion of an investigation and prior to the filing of an Administrative Complaint. The notice of violation will advise the alleged violator of the statutory violations and provide a proposed penalty for settlement of the disciplinary matters related to a complaint. Upon issuing the notice of violation to an alleged violator, the Department will provide instructions on when and how the alleged violator can settle the disciplinary matter by accepting the notice of violation.

(9) No provision in this section will prevent or restrict the Department from denying a permit, registration or certification based on any provision of Chapter 499, F.S., that authorizes such action.

(10) No provision of this section will prevent or restrict the Department’s authority to enter into any settlement agreement concerning violations of Chapter 499, F.S., or this rule chapter, pursuant to the authority of Section 120.57(4), F.S.

**61N-1.0245 Notification of Noncompliance; Minor Violations.**

(1) In accordance with Section 120.695, F.S., the Department of Business and Professional Regulation (hereinafter the “Department”) may issue a notice of noncompliance to a licensee, registrant or permitholder for an initial offense of a minor violation.

(2) The Department designates a violation of subsection 61N-1.012(5), F.A.C. – Failure to maintain a copy of the Florida Drug and Cosmetic Act, Chapter 499, Part I, F.S., and Chapter 61N-1, F.A.C., Regulations for Drugs, Devices and Cosmetics, at the permitted establishment, as a minor violation for which a notice of noncompliance may be issued.

(3) The designation of a minor violation for purposes of Section 120.695, F.S., is limited to only initial violations in which corrective action is commenced within 14 days after the licensee, registrant or permitholder’s receipt of the Department’s issuance of a notice of noncompliance. The failure of a licensee, registrant or permitholder to comply with the notice of noncompliance within the prescribed period of time shall no longer be deemed a minor violation and shall be treated as a disciplinary violation pursuant to Section 499.066, F.S., and/or Rule 61N-1.024, F.A.C. Violations of this section shall be handled in accordance with the standard disciplinary guidelines of the Department. Nothing provided in this section shall restrict the Department from seeking full administrative action in such instances where aggravating circumstances are present which would preclude a minor violation dismissal.

(4) The notice of noncompliance may be delivered to the licensee, registrant or permitholder’s current mailing address by certified mail, by restricted delivery or by personal service. The notice of noncompliance may also be...
61N-1.025 Certification Authority and Digital Signatures for Self-Authenticating Electronic Pedigree.

(1) As used in this rule chapter the terms “certificate” and “Certification Authority” are as defined by Section 668.003, F.S. (2005). The department will list on its website one or more companies authorized to serve as a Certification Authority to issue digital certificates to persons for purposes of certifying via a digital signature the accuracy and completeness of a pedigree paper for authentication purposes under sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C. The department recognizes that a Certification Authority listed on the department’s website may revoke any digital certificate it has issued. In addition, the department recognizes that the certificate holder and the employer of the certificate holder may also seek revocation of a certificate, for example because of termination of the holder’s employment or change of the holder’s authority to sign a pedigree for the employing establishment.

(2) The department will list on its website a Certification Authority that requests in writing to the bureau that it be so listed, if the request demonstrates:

(a) The Certification Authority meets the requirements set forth in the Federal Government Bridge Certification Authority Certificate Policy (FBCA CP), of the federal General Services Administration for “medium assurance” certificates, or comparable requirements.

(b) The Certification Authority will issue two types of certificates the status of which is ascertainable within the digital signature. One type of certificate will indicate that the person to whom the digital signature is issued signs on behalf of a company that is lawfully permitted in Florida to engage in the unrestricted wholesale distribution of a prescription drug in or into Florida. The other type of certificate will indicate that the person to whom the digital signature is issued signs on behalf of a company that is not lawfully permitted in Florida but is lawfully permitted in its resident state to engage in the wholesale distribution of prescription drugs, or is licensed in Florida under a restricted distributor permit.

(c) The Certification Authority requires at a minimum the following written documentation prior to granting a digital certificate to the person requesting a digital signature to sign an electronic pedigree:

1. Authorization from the establishment for whom the person is requesting a digital certificate that that person may sign pedigree papers on the establishment’s behalf,

2. A valid, unexpired identification document which bears a photograph of the person requesting a digital certificate such as:

   a. A passport issued by the United States, an immigration document issued by the Federal Government, or any document issued by an agency of the Federal Government or the Armed Services of the United States,

   b. A passport issued by a foreign government if the passport includes or is accompanied by a document proving that the alien is lawfully in the United States, or

   c. A document issued by a state or political subdivision if the issuing state or political subdivision prohibits the issuance of the identification document to an alien who is unlawfully in the United States, and the state or political subdivision requires independent verification of the records offered by the person to prove identity when applying for the identification document.

3. A copy of the state issued permit for the company’s name and address for whom the person is requesting a digital certificate demonstrating authorization by the state of Florida to engage in the unrestricted wholesale distribution of prescription drugs in or into Florida, or

   b. A copy of the state issued permit or license for the company’s name and address for whom the person is requesting a digital certificate demonstrating authorization by the state in which the company resides to engage in the wholesale distribution of prescription drugs, or demonstrating authorization by the state of Florida to engage in the wholesale distribution of prescription drugs under a restricted distributor permit.

(d) The Certification Authority shall submit to the department a statement from an independent auditor confirming that the Certification Authority complies with the requirements of this rule and the applicable provisions of subparagraph 61N-1.013(5)(d)1., F.A.C., so that a recipient of a pedigree signed with a digital signature issued by the Certification Authority can rely on the integrity of the digital signature.
(3) To remain listed as a Certification Authority on the department’s website, the Certification Authority must submit a signed statement certifying to the department on an annual basis that it operates in accordance with the requirements of this section and has been audited by a qualified independent (from the operator of the Certification Authority) auditor on at least an annual basis. The Certification Authority must also submit a signed statement from an independent auditor that the Certification Authority complies with the requirements of this rule and the applicable provisions of sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C. This documentation must be submitted to the department by June 1 of each year in order to remain listed on the department’s website as a Certification Authority for the next July 1 – June 30 period.

(4) If a Certification Authority proposes comparable requirements to the FBCA CP “medium assurance” certificates, the Certification Authority must provide a detailed crosswalk between the standards set forth for the FBCA CP “medium assurance” certificates and the proposed comparable requirements with a detailed explanation describing how the comparable requirements provide at least the same level of assurance as the FBCA CP standards.

(5) If any of the requirements in the FBCA CP differ from those set forth in this rule, the ones set forth in this rule shall prevail.

(6) If authorized by the affected establishments that lawfully purchase or receive prescription drugs to digitally sign their electronic pedigrees, an employee may be issued digital certificates for each such establishment or for multiple permits of a single establishment.

(7)(a) The loss, theft, or compromise of a private key or password must be communicated to the Certification Authority within 24 hours of discovery of the key’s loss, theft, or compromise. Notification should promptly result in a request for revocation of the Certificate holder’s digital certificate and must include sufficient information to uniquely identify the certificate holder. Revocation shall be effective upon issuance of the next Certificate Revocation List.

(b) During the lifetime of the certificate, the Certificate Authority must for each certificate issued verify the license status has not been suspended, revoked, or otherwise inactivated for the wholesale distribution of prescription drugs. The Certificate Authority must perform this check at least weekly. If it is found the license status has been suspended, revoked, or otherwise inactivated, then the Certificate Authority must issue a certificate revocation for all certificates issued effective the date of the license change.

(8) Either the certificate holder or the establishment shall request revocation of a certificate holder’s digital certificate upon termination of the certificate holder’s authorization to make digital signatures on behalf of the establishment. Notification should promptly request revocation of the certificate holder’s digital certificate and must include sufficient information to uniquely identify the certificate holder. Revocation shall be effective upon issuance of the next Certificate Revocation List.

(9) The establishment is ultimately responsible for electronic pedigrees that have been digitally signed on its behalf.

(10) Until a Certification Authority can submit the audit required in paragraph (2)(d) or June 30, 2007, whichever is earlier, the Department will provisionally list a Certification Authority requesting to be listed on the Department’s website www.myfloridalicense.com as a Certification Authority, provided that the Certification Authority submits the audit required by paragraph (2)(d) by June 15, 2007, and otherwise operates in accordance with the requirements of this rule. A digital certification issued by a provisionally listed Certification Authority must expire and be revoked on or before June 30, 2007. Any provisionally listed Certification Authority that has not submitted the audit required in paragraph (2)(d) by June 15, 2007, will be removed from the provisional list and may not operate as a Certification Authority under this section. Upon submission of the audit required by paragraph (2)(d), the Certification Authority will be listed without the provisional designation. Upon removal of the provisional designation, a Certification Authority must reissue all existing digital certificates.

Rulemaking Authority 499.003, 499.0121, 499.0122, 499.013, 499.014, 499.05 FS. Law Implemented 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.051, 499.052 FS. History–New 8-6-06, Amended 9-5-07, Formerly 64F-12.025.

61N-1.026 Cancer Drug Donation Program.
The purpose of this section is to establish and maintain a cancer drug donation program under which unused cancer prescription drugs and cancer supplies may be donated and dispensed to eligible individuals who are diagnosed with
cancer. This rule applies to the department or any person who donates, receives, dispenses or otherwise participates
or wishes to participate in the cancer drug donation program.
(1) Recipient Eligibility Requirements.
(a) A Florida resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug
donation program unless the person falls under paragraph 61N-1.026(1)(b), F.A.C.
(b) A Florida resident is ineligible to participate in the cancer drug donation program if the person is eligible to
receive cancer drugs or supplies through the Medicaid program, third-party insurer or any other prescription drug
program funded in whole or in part by the Federal Government, unless these benefits have been exhausted, or a
certain cancer drug or supply need by the patient is not covered by the prescription drug program as stated in Section
499.029(9), F.S.
(2) Donor Eligibility Requirements. Any person defined as a donor in Section 499.029(3), F.S., is determined to be
eligible to be a donor.
(3) Participant Facility Requirements.
(a) Eligibility: Only a Class II Institutional Pharmacy, permitted under Chapter 465, F.S., that accepts, stores and
dispenses donated cancer drugs and supplies may participate in the cancer drug donation program.
(b) Notice of Participation: Participation in the cancer drug donation program is voluntary. To be eligible for
participation in the cancer drug donation program, a Class II Institutional Pharmacy must elect to participate and
provide the department with all of the following as set forth in Form DH-MQA 1100, 2/07, incorporated by
reference in subsection (4):
1. The name, permit number, street address, and telephone number of the pharmacy,
2. The name and telephone number of a pharmacist or another contact as determined by the pharmacist who is
employed by or under contract with the pharmacy,
3. A statement indicating the pharmacy meets the eligibility requirements under paragraph (3)(a), herein.
(c) Withdrawal from participation: A pharmacy may withdraw from participation in the cancer drug donation
program upon at least 10 days written notification to the department as set forth in Form DH-MQA 1100, 2/07,
incorporated by reference in subsection (4).
(d) Storage: Cancer drugs and supplies donated under the cancer drug donation program shall be stored in a secure
storage area under environmental conditions appropriate for the cancer drugs or supplies being stored. Donated
cancer drugs and supplies may not be stored with non-donated inventory.
(e) Dispensing:
1. Cancer drugs and supplies shall be dispensed by a licensed pharmacist, whether or not employed by or under
contract with a participant facility, pursuant to the requirements in Chapter 465, F.S.,
2. The pharmacist shall inspect the donated cancer drugs and supplies for adulteration, misbranding, mislabeling,
and the date of expiration before dispensing. Cancer drugs or supplies that are tampered with, expired, adulterated,
mislabeled or misbranded may not be dispensed,
3. Before a cancer drug or supply may be dispensed to a recipient, the recipient shall sign a cancer drug donation
program Recipient Record, Form DH-MQA 1098, 2/07, incorporated by reference in subsection (4), and shall be
notified, both orally and in writing, that the cancer drug or supply may have been previously dispensed,
4. Cancer drugs and supplies shall be dispensed only to recipients who meet the following eligibility requirements:
   a. Individuals who are uninsured,
   b. All other individuals who are otherwise eligible under subsection (1), herein, to receive cancer drugs or supplies
      from the cancer drug donation program.
5. Cancer drugs or supplies may not be donated to a specific cancer patient.
(f) Recordkeeping requirements:
1. Donor and Recipient Records as reflected in Forms DH-MQA 1099, 2/07 and 1098, 2/07, incorporated by
reference in subsection (4), shall be maintained at least 3 years by the participant facility.
2. Destruction Records for donated drugs or supplies as reflected in Form DH-MQA 1099, 2/07, incorporated by
reference in subsection (4), shall be maintained at least 3 years by the participant facility. For each drug or supply
destroyed the record shall include all of the following information:
a. The date of destruction,
b. The name, strength and quantity of the cancer drug destroyed,
c. The name of the person or firm that destroyed the drug,
d. The source of the drugs or supplies destroyed.

(4) Required Forms for Program Participants.
(a) Cancer Drug Donation Program Recipient Record, DH-MQA 1098, effective February 2007 and incorporated herein by reference.
(b) Cancer Drug Donation Program Donation and Destruction Record, DH-MQA 1099, effective February 2007, and incorporated herein by reference.
(c) Cancer Drug Donation Program Notice of Participation or Withdrawal, DOH Form DH-MQA 1100, effective February 2007, and incorporated herein by reference.

The above referenced required forms are available by contacting the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, or by downloading them from the department’s website.

(5) Dispensing Fees. A cancer drug donation program participant facility may charge the recipient of the drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee or no more than $15.00, whichever is less, for each cancer drug or supply dispensed.

(6) Categories of drugs and supplies eligible for donation.
(a) Cancer drugs. A cancer drug is eligible for donation under the cancer drug donation program only if all the following requirements are met:
1. The donation is accompanied by a completed cancer drug donation program Donation Record that is signed by the person making the donation or that person’s authorized representative,
2. The drug’s expiration date is at least 6 months later than the date that the drug was donated and its tamper resistant packaging is intact,
3. The drug is in its original, unopened, sealed, tamper-evident unit dose packaging that includes the drug’s lot number and expiration date. Single-unit dose drugs may be accepted if the single-unit dose packaging is unopened,
4. Cancer drugs billed to and paid for by Medicaid in long-term care facilities are not eligible for donation unless not reimbursable by Medicaid.
(b) Cancer supplies. Cancer supplies are eligible for donation under the cancer drug donation program only if the supplies meet all the following requirements:
1. The supplies have not been tampered with or mislabeled; the supplies are in their original, unopened, sealed packaging,
2. The donation is accompanied by a completed cancer drug donation program Donation Record that is signed by the person making the donation or that person’s authorized representative.
(c) Drugs and supplies not eligible for donation. All of the following drugs are ineligible for donation or acceptance under the cancer drug donation program.
1. Substances listed in Schedule II, Schedule III, Schedule IV or Schedule V of Section 893.03, F.S.,
2. Drugs and supplies that do not meet the criteria under paragraphs (6)(a) and (b), herein,
3. Drugs that expire less than 6 months after the date of donation.

(7) The Department shall establish a website to maintain the registry of participant facilities. The website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

Rulemaking Authority 499.029(8) FS. Law Implemented 499.029 FS. History–New 8-6-07, Formerly 64F-12.026.

61N-1.027 Distribution of Medical Oxygen for Emergency Use.
(1) “Emergency use” means the administration of oxygen USP to an individual that is experiencing an unexpected, life-threatening, medical situation which requires immediate action.
(2) “Persons authorized to receive emergency use oxygen” means:
(a) A person experiencing an unexpected, life-threatening, medical situation due to oxygen deficiency and requiring resuscitation;
(b) A person exempted pursuant to Section 499.03, F.S.; and,
(c) Business establishments, universities, schools, and other such entities or organization conducting lawful activities which include frequent contact or interaction with members of the public, e.g. banks, hotels, restaurants, recreation camps, theme parks and resorts, and sports arenas. These establishments must employ an individual that has training on the use and administration of emergency use oxygen.
(3) “Transfilling” means transferring the gas, either in a liquid or gaseous state, from a larger container into smaller containers (i.e., high-pressure cylinders or cryogenic vessels).
(4) A Florida-permitted prescription drug manufacturer, prescription drug repackager or medical gas manufacturer may transfill and distribute a medical oxygen cylinder to persons authorized to receive emergency use oxygen for emergency use.
(5) A Florida-permitted medical gas wholesale distributor or medical oxygen retail establishment may distribute a medical oxygen cylinder to persons authorized to receive emergency use oxygen for emergency use.
(6) Entities distributing emergency use oxygen pursuant to this rule must:
(a) Have a current permit, or have a permit that is undergoing renewal and allowed to continue to operate during the division’s review and processing of the renewal;
(b) Have a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributions set forth in Section 499.90, F.S.;
(c) Include the statement on the cylinder or vessel label: “For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, prescription statement.” The Prescription statement is “Rx Only” or the prescription symbol followed by the word “Only”; and,
(d) Create contemporaneously with and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in Section 499.89, F.S. If the distribution is to a person that does not have a license or permit, the establishment is not required to include the purchaser’s license or permit number and its expiration date in the records. The record, including the invoice or delivery ticket, shall indicate that the distribution was for “emergency use” in the permit number field of the audit trail outbound document.
(7) Establishments distributing “emergency use” oxygen pursuant to this rule shall comply with the container labeling requirements and good manufacturing practices of the United State Food, Drug and Cosmetic Act, 21 U.S.C., Chapter 9, and Rule 61N-1.007, F.A.C.


61N-1.028 Product Tracking and Tracing – Definitions.
The following definitions apply to the product tracking and tracing requirements set forth in Rules 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.
(1) “AFFILIATE” means a business entity that has a relationship with a second business entity if, directly or indirectly:
(a) One business entity controls, or has the power to control, the other business entity, or
(b) A third party controls, or has the power to control, both of the business entities.
(2) “AUTHORIZED” means:
(a) A manufacturer or repackager, registered as a drug establishment with the FDA;
(b) A wholesale distributor, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 353(e), (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06713;
(c) A third-party logistics provider, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 360eee-3(b) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06714; and,
(d) A dispenser, having a valid license under Florida law.
(3) “DISPENSER” means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or
administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. Dispenser does not include a person who dispenses only products to be used in animals when the product is dispensed on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship.

(4) “DISPOSITION” means, with respect to a product within the possession or control of an entity, the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other handling or actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) “DISTRIBUTE” or “DISTRIBUTION” means to sell, purchase, trade, deliver, handle, store, or receive a product. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(6) “EXCLUSIVE DISTRIBUTOR” means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

(7) “GRANDFATHERED” means, with respect to a product, a product that is not labeled with a product identifier and that entered the pharmaceutical distribution supply chain on or before March 1, 2016.

(8) “HOMOGENOUS CASE” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(9) “ILLEGITIMATE PRODUCT” means a product that:
(a) Is counterfeit, diverted, or stolen;
(b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is the subject of a fraudulent transaction, or
(d) Appears unfit for distribution such that the product would likely result in serious adverse health consequences or death to humans.

(10) “LICENSED” means having a valid license in accordance with Florida law. For the purposes of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C., a dispenser is considered “licensed” if the dispenser has a valid license under Florida law.

(11) “MANUFACTURER” means:
(a) A person that holds an application approved under 21 U.S.C. 355 (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06715, or a license issued under section 351 of the Public Health Service Act (42 U.S.C. s. 262) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06716, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
(b) A co-licensed partner or affiliate of a person described in paragraph 61N-1.028(11)(a), F.A.C., that obtains the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(c), F.A.C., or
(c) An affiliate of a person described in paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C., that receives the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C.

(12) “MEDICAL CONVENIENCE KIT” means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06712.
A “medical convenience kit” is considered an “exempt medical convenience kit” if it is a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, and:
(a) The kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with 21 U.S.C. s. 360(b)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06717;
(c) If the kit includes a product:
   1. The person that manufacturers the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer and did not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and,
   2. The product is:
      a. An intravenous solution intended for the replenishment of fluids and electrolytes,
      b. A product intended to maintain the equilibrium of water and minerals in the body,
      c. A product intended for irrigation or reconstitution,
      d. An anesthetic,
      e. An anticoagulant,
      f. A vasopressor, or
      g. A sympathomimetic.

(13) “PACKAGE” means the smallest individual saleable unit of product for distribution by a manufacturer or repacker that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this paragraph, an “individual saleable unit” is the smallest container of product introduced into commerce by the manufacturer or repacker that is intended by the manufacturer for individual sale to a dispenser.


(15) “PRODUCT IDENTIFIER” means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product. Unless authorized by the department, the applicable data shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon a package and homogeneous case.

(16) “QUARANTINE” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use.

(17) “REPACKAGER” means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.

(18) “RETURN” means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

(19) “RETURNS PROCESSOR or REVERSE LOGISTICS PROVIDER” means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(20) “SPECIFIC PATIENT NEED” refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to
another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(21) “STANDARDIZED NUMERICAL IDENTIFIER” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(22) “SUSPECT PRODUCT” means a product for which there is reason to believe that such product:
(a) Is potentially counterfeit, diverted, or stolen;
(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is potentially the subject of a fraudulent transaction, or
(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(23) “THIRD PARTY LOGISTICS PROVIDER” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(24) “TRADING PARTNER” means:
(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product, or
(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(25) “TRANSACTION.”
(a) The term “transaction” means the transfer of product between persons in which a change of ownership occurs.
(b) EXEMPTIONS. The term “transaction” does not include:
1. Intracompany distribution of any product between members of an affiliate or within a manufacturer,
2. The distribution of a product among hospitals or other health care entities that are under common control,
3. The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. s. 247d) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06724, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
4. The dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C. s. 353(b)(1) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06725,
5. The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with 21 U.S.C. s. 353(d) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06726.
6. The distribution of blood or blood components intended for transfusion,
7. The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use,
8. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. s. 501(c)(3) (Internal Revenue Code) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06727, to a nonprofit affiliate of the organization to the extent otherwise permitted by law,
9. The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors,
11. Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2021) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06720.

   a. A product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity,
   b. 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product, or
   c. 2 or more finished medical devices plus one or more drug or biological products that are packaged together in a “medical convenience kit,”

13. The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.,
14. The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids),
15. The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions,
16. The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection,

(26) “TRANSACTION HISTORY” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction history for a grandfathered product begins with the owner of the product on January 1, 2015.

(27) “TRANSACTION INFORMATION” means:
   (a) The proprietary or established name or names of the product;
   (b) The strength and dosage form of the product;
   (c) The National Drug Code number of the product;
   (d) The container size;
   (e) The number of containers;
   (f) The lot number of the product;
   (g) The date of the transaction;
   (h) The date of the shipment, if more than 24 hours after the date of the transaction;
   (i) The business name and address of the person from whom ownership is being transferred; and,
   (j) The business name and address of the person to whom ownership is being transferred.

(28) “TRANSACTION STATEMENT” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
   (a) Is authorized as required under this chapter;
   (b) Received the product from a person that is authorized as defined in subsection 61N-1.028(2), F.A.C.;
   (c) Received transaction information and a transaction statement from the prior owner of the product, as required under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
(d) Did not knowingly ship a suspect or illegitimate product;
(e) Had systems and processes in place to comply with verification requirements under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
(f) Did not knowingly provide false transaction information; and,
(g) Did not knowingly alter the transaction history.

The owner of a grandfathered product is exempt from asserting receipt of transaction information and transaction statement from the prior owner.

(29) “VERIFICATION” or “VERIFY” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

(30) “WHOLESALE DISTRIBUTION” means the distribution of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, to a person other than a consumer or patient, or receipt of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, by a person other than the consumer or patient, but does not include:
(a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;
(b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
(c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to 42 U.S.C. s. 247d (section 319 of the Public Health Service Act) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06724, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
(e) The distribution of minimal quantities of drug by a licensed community pharmacy that is a retail pharmacy to a licensed practitioner for office use;
(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
(h) The distribution of a drug by the manufacturer of such drug;
(i) The receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;
(j) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
(k) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with 21 U.S.C. s. 360eee-1(e) (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06732.
(l) Saleable drug returns when conducted by a dispenser;
(m) The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;
(n) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
(o) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
(p) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
(r) Facilitating the distribution of a product by providing solely administrative services, including processing of
orders and payments, or

(s) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in 21 U.S.C. s. 360eee(16)(B) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06732, and registered under 21 U.S.C. s. 360 (as of 12/1/15), which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06731, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(31) “WHOLESALE DISTRIBUTOR” means a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-16-16.

61N-1.029 Product Tracking and Tracing – Manufacturer Requirements.
The following tracking and tracing requirements shall apply to manufacturers:

(1) PRODUCT TRACING.
   (a) A manufacturer shall, prior to or at the time of each transaction in which such manufacturer transfers ownership of a product:
      1. Provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in a paper or electronic format;
      2. Capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction; and,
      3. Maintain such information, history, and statement for not less than 6 years after the date of the transaction.
   (b) Requests For Information. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.
   (c) Electronic Format. Effective December 1, 2017, a manufacturer shall provide the transaction information, transaction history, and transaction statement required under paragraph 61N-1.029(1)(a), F.A.C., in an electronic format. A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under paragraph 61N-1.029(1)(a), F.A.C., in a paper format to a licensed health care practitioner authorized to prescribe medication under Florida law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.
   (d) Product Identifier. Effective December 1, 2017, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction. A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

(2) AUTHORIZED TRADING PARTNERS. The trading partners of a manufacturer may only be authorized trading partners.

(3) VERIFICATION. The department adopts and incorporates by reference the manufacturer verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(b)(4) http://www.flrules.org/Gateway/reference.asp?No=Ref-06759, (as of 12/1/15). A manufacturer must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the manufacturer will meet the federal verification requirements as adopted by the department.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.

61N-1.030 Product Tracking and Tracing – Wholesale Distributor Requirements.
The following tracking and tracing requirements shall apply to wholesale distributors:

(1) PRODUCT TRACING.
(a) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this paragraph.

(b) A wholesale distributor that purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, provide to the subsequent purchaser:
1. A transaction statement, which shall state that the wholesale distributor, or a member of the affiliate of the wholesale distributor, purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer; and,
2. The transaction history and transaction information.
3. If provided to a dispenser, the transaction history, transaction information, and transaction statement shall be on a single document in a paper or electronic format.
4. If provided to a wholesale distributor, the transaction history, transaction information, and transaction statement shall be through any combination of self-generated paper, electronic data, or manufacturer provided information on the product package.
5. The lot number of the product, the initial transaction date and the initial shipment date from the manufacturer are not required to be included in the transaction history and information for transactions falling under paragraph 61N-1.030(1)(b), F.A.C.

(c) A wholesale distributor that did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction or subsequent transaction, provide to the subsequent purchaser, a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the requirements set forth in the departmental rules.
1. The transaction history supplied shall begin only with the wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer.
2. The wholesale distributor that did not purchase directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer, shall inform the subsequent purchaser that the wholesale distributor received a direct purchase statement from a wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer.

(d) A wholesale distributor shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in this rule and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and maintain the confidentiality of the transaction information, including any lot level information, transaction history, and transaction statement for a product and prohibit disclosure to any person other than state or federal officials, except to comply with the provisions of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.

(2) RETURNS.

(a) Saleable Returns. Notwithstanding paragraph 61N-1.030(1)(a), F.A.C., the following shall apply:
1. Requirements. Until December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and notwithstanding paragraph 61N-1.030(1)(b), F.A.C., may distribute the returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of the product shall begin with the wholesale distributor that accepted and verified the returned product, consistent with the requirements of this rule.
2. Enhanced Requirements. Beginning December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate the returned product with the transaction information and transaction statement associated with that product. For all transactions after December 1, 2019, the transaction history, as applicable, of the product shall begin with the wholesale distributor that accepted and verified the returned product.
(b) Nonsaleable Returns. A wholesale distributor may return a nonsaleable product to the manufacturer or repackage, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under paragraph 61N-1.030(1)(a), F.A.C.

(3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(4) TRADING PARTNER AGREEMENTS. Effective December 1, 2019, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subsection shall be construed to limit the applicability of subsections 61N-1.030(1) through 61N-1.030(3), F.A.C.

(5) PRODUCT IDENTIFIER. Effective December 1, 2019, a wholesale distributor may engage in transactions involving a product only if that product is encoded with a product identifier or grandfathered as defined by subsection 61N-1.028(7), F.A.C., and not required to be encoded with a product identifier.

(6) AUTHORIZED TRADING PARTNERS. The trading partners of a wholesale distributor may only be authorized trading partners.

(7) VERIFICATION. The department adopts and incorporates by reference the wholesale distributor verification requirements as set forth in the federal act at 21 U.S.C. § 360eee-1(c)(4)
http://www.flrules.org/Gateway/reference.asp?No=Ref-06761 (as of 12/1/15). A wholesale distributor must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the wholesale distributor will meet the federal verification requirements as adopted by the department.

(8) Drop Shipment.

(a) A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this rule, except the federal notification requirements adopted under subsection 61N-1.030(7), F.A.C., provided that the manufacturer, repackage, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser, the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

(b) Drop shipment by the wholesale distributor to trading partners, other than to a dispenser, is not exempt from the provisions of this rule.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.

61N-1.031 Product Tracking and Tracing – Dispenser Requirements.
The following tracking and tracing requirements shall apply to dispensers:

(1) PRODUCT TRACING.

(a) A dispenser shall not accept ownership of a product, unless the previous owner prior to or at the time of the transaction, provides transaction history, transaction information, and a transaction statement;

(b) A dispenser shall, prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product, excluding dispensing to a patient or returns, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this rule shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and,

(c) A dispenser shall capture transaction information, including lot level information, if provided, transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

(2) AGREEMENTS WITH THIRD PARTIES. – A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements, required to be maintained under this rule, on behalf of
the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of a dispenser under this rule.

(3) RETURNS.
(a) Saleable Returns. A dispenser may return a product to the trading partner from which the dispenser obtained the product without providing the information required under paragraph 61N-1.031(1)(b), F.A.C.
(b) Nonsaleable Returns. A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subsection 61N-1.031(1), F.A.C.

(4) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request, provide the applicable transaction information, transaction statement, and transaction history that the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or the wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

(5) PRODUCT IDENTIFIER. Effective December 1, 2020, a dispenser may engage in transactions involving a product only if the product is encoded with a product identifier or grandfathered, as defined by subsection 61N-1.028(7), F.A.C., and is not required to be encoded with a product identifier.

(6) AUTHORIZED TRADING PARTNERS. The trading partners of a dispenser may be only authorized trading partners.

(7) VERIFICATION. The department adopts and incorporates by reference the dispenser verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(d)(4) http://www.flrules.org/Gateway/reference.asp?No=Ref-06762 (as of 12/1/15). A dispenser must establish, maintain, and adhere to written polices and procedures setting forth the manner in which the dispenser will meet the federal requirements as adopted by the department.

(8) EXCEPTION. Notwithstanding any other provision of law, the requirements under subsections 61N-1.031(1) through (4), and (7), F.A.C., shall not apply to licensed health care practitioners authorized to prescribe or administer medication under Florida law or other licensed individuals under the supervision or direction of practitioners who dispense or administer products in the usual course of professional practice.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.

61N-1.032 Product Tracking and Tracing – Repackager Requirements.
The following tracking and tracing requirements shall apply to repackagers:

(1) PRODUCT TRACING.
(a) A repackager shall not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product.
(b) A repackager, prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product.
(c) A repackager shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in paragraphs 61N-1.032(1)(a) and (1)(b), F.A.C., and shall maintain such information, history, and statement for not less than 6 years after the transaction.

(2) RETURNS.
(a) Nonsaleable Product. A repackager may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such manufacturer, repackager or wholesale distributor, including a returns processor, without providing the information required under paragraph 61N-1.032(1)(b), F.A.C.
(b) Saleable or Nonsaleable Product. A repackager may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom the product was received without providing the information
required under paragraph 61N-1.032(1)(b), F.A.C., on behalf of the hospital or other health care entity that took
ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the
entity that owns the product.

(3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose
of investigating a suspect product or an illegitimate product, a repackager shall, not later than 1 business day, and
not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction
history, and transaction statement for the product.

(4) PRODUCT IDENTIFIER. Beginning December 1, 2018, a repackager shall:
(a) Affix or imprint a product identifier to each package and homogenous case of product intended to be introduced
in a transaction in commerce;
(b) Maintain the product identifier information for such product for not less than 6 years after the date of the
transaction;
(c) Engage in transactions involving a product only if such product is encoded with a product identifier or
grandfathered as defined by subsection 61N-1.028(7), F.A.C., and is not required to be encoded with a product
identifier; and,
(d) Maintain records for not less than 6 years.
A repackager is not required to affix or imprint a unique device identifier on a package that is required to have a
standardized numerical identifier.

(5) AUTHORIZED TRADING PARTNERS. The trading partners of a repackager may only be authorized trading
partners.

(6) VERIFICATION. The department adopts and incorporates by reference the repackager verification requirements
as set forth in the federal act at 21 U.S.C. s. 360eee-1(e)(4) [http://www.frlrules.org/Gateway/reference.asp?No=Ref-
06763](http://www.frlrules.org/Gateway/reference.asp?No=Ref-06763) (as of 12/1/15). A repackager must establish, maintain, and adhere to written policies and procedures setting
forth the manner in which the repackager will meet the federal verification requirements as adopted by the
department.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.
Title 21: Food and Drugs

Part 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

§205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§205.3 Definitions.

(a) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) Blood component means that part of blood separated by physical or mechanical means.

(c) Drug sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) Prescription drug means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) Wholesale distribution and wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, emergency medical reasons includes
transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with §203.23 of this chapter; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(g) Wholesale distributor means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(h) Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in §203.22(h) and (i) of this chapter, a person cannot simultaneously be a “health care entity” and a retail pharmacy or wholesale distributor.

§205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. (1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at “controlled” room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) Examination of materials. (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all
incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs. (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Recordkeeping. (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and
inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Compliance with Federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.
§205.6 Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper
operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature,
sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged,
deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary
containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. (1) All facilities used for wholesale drug distribution shall be secure from
unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection
against theft and diversion. When appropriate, the security system shall provide protection
against theft or diversion that is facilitated or hidden by tampering with computers or electronic
records.

(c) Storage. All prescription drugs shall be stored at appropriate temperatures and under
appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or
with requirements in the current edition of an official compendium, such as the United States
Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at
“controlled” room temperature, as defined in an official compendium, to help ensure that its
identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording
equipment, devices, and/or logs shall be utilized to document proper storage of prescription
drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all
stored drugs.

(d) Examination of materials. (1) Upon receipt, each outside shipping container shall be visually
examined for identity and to prevent the acceptance of contaminated prescription drugs or
prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to
reveal container damage that would suggest possible contamination or other damage to the
contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs. (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Recordkeeping. (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.
(g) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Compliance with Federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of
any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.
§321. Definitions; generally

For the purposes of this chapter—

(a)(1) The term "State," except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on
the body of man or other animals and which is not dependent upon being metabolized for the
achievement of its primary intended purposes. The term "device" does not include software
functions excluded pursuant to section 360j(o) of this title.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or
sprayed on, introduced into, or otherwise applied to the human body or any part thereof for
cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles
intended for use as a component of any such articles; except that such term shall not include
soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official
Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any
supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate
container of any article; and a requirement made by or under authority of this chapter that any
word, statement, or other information appear on the label shall not be considered to be complied
with unless such word, statement, or other information also appears on the outside container or
wrapper, if any there be, of the retail package of such article, or is easily legible through the
outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon
any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading,
then in determining whether the labeling or advertising is misleading there shall be taken into
account (among other things) not only representations made or suggested by statement, word,
design, device, or any combination thereof, but also the extent to which the labeling or
advertising fails to reveal facts material in the light of such representations or material with
respect to consequences which may result from the use of the article to which the labeling or
advertising relates under the conditions of use prescribed in the labeling or advertising thereof
or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a
representation that it is a germicide, except in the case of a drug purporting to be, or
represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or
such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new
animal drug) the composition of which is such that such drug is not generally recognized,
among experts qualified by scientific training and experience to evaluate the safety and
effectiveness of drugs, as safe and effective for use under the conditions prescribed,
recommence, or suggested in the labeling thereof, except that such a drug not so
recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it
was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its
labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new
animal drug) the composition of which is such that such drug, as a result of investigations to
determine its safety and effectiveness for use under such conditions, has become so
recognized, but which has not, otherwise than in such investigations, been used to a material
extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any
substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and
Rodenticide Act [7 U.S.C. 136 et seq.], including all active and inert ingredients of such
pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—
(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than sections 342(a)(2)(B) and 346a of this title.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

1. a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
2. a pesticide chemical; or
3. a color additive; or
4. any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
5. a new animal drug; or
6. an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural
physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, 360ccc, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w) of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.
(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer’s report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of title 42.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical;
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—
(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or
(ii) complies with section 350(c)(1)(B)(ii) of this title;
(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
(C) is labeled as a dietary supplement; and

(3) does—
(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and
(B) not include—
(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.  

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.  

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—
(1) means a drug that—
(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and
(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlorotetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(ck) Priority supplement.—The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
(B) A food ingredient that is exempt under paragraph (6) or (7) of section 343(w) of this title.

(rr)(1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.

(3) The products described in paragraph (2) shall be subject to subchapter V of this chapter.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).


REFERENCES IN TEXT


complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Poultry Products Inspection Act, referred to in par. (s)(4), is Pub. L. 85–172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (§451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Meat Inspection Act of March 4, 1907, as amended and extended, referred to in par. (s)(4), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90–201, 81 Stat. 584, which are classified generally to subchapters I to IV (§601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Section 101(4) of the Food and Drug Administration Modernization Act of 1997, referred to in par. (kk), is section 101(4) of Pub. L. 105–115, which is set out as a note under section 379g of this title.

**AMENDMENTS**

2016—Subsec. (h). Pub. L. 114–255 inserted at end of concluding provisions "The term 'device' does not include software functions excluded pursuant to section 360j(o) of this title."


2007—Par. (ff). Pub. L. 110–85 substituted "paragraph (g) and section 350f of this title" for "paragraph (g)" in concluding provisions.


Pars. (ll), (mm). Pub. L. 107–250 added pars. (ll) and (mm).

1998—Par. (q)(1). Pub. L. 105–324, §2(a), added subpar. (1) and struck out former subpar. (1) which read as follows: "The term 'pesticide chemical' means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide."

Par. (q)(3). Pub. L. 105–324, §2(c), substituted "subparagraphs (1) and (2)" for "paragraphs (1) and (2)" in introductory provisions.


1996—Par. (q). Pub. L. 104–170, §402(a), amended par. (q) generally. Prior to amendment, par. (q) read as follows: "The term 'pesticide chemical' means any substance which, alone, in chemical combination or in formulation with one or more other substances, is 'a pesticide' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities."

Par. (s)(1), (2). Pub. L. 104–170, §402(b), amended subpars. (1) and (2) generally. Prior to amendment, subpars. (1) and (2) read as follows:

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or".

Pars. (gg), (hh). Pub. L. 104–170, §402(c), added pars. (gg) and (hh).

1994—Par. (g)(1). Pub. L. 103–417, §10(a), amended last sentence generally. Prior to amendment, last sentence read as follows: "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."


1993—Pars. (c), (d). Pub. L. 103–80, §3(dd)(1), substituted "Health and Human Services" for "Agriculture".


See 1992 amendment note below.

Pars. (v) to (ff). Pub. L. 103–80, §3(b), redesignated pars. (w) to (ff) as (v) to (ee), respectively.

1992—Pars. (c), (d). Pub. L. 102–300, §6(b)(1), which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions notes below.


Par. (u). Pub. L. 102–571 substituted "379e" for "376".


1990—Par. (g)(1). Pub. L. 101–629, §16(b)(1), struck out "; but does not include devices or their components, parts, or accessories" after "clause (A), (B), or (C)".
Pub. L. 101–535 inserted at end "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."

Par. (h)(3). Pub. L. 101–629, §16(b)(2), which directed the amendment of subpar. (3) by substituting "its primary" for "any of its principal", could not be executed because "any of its principal" did not appear in subpar. (3).

1988—Par. (w)(3). Pub. L. 100–670 struck out subpar. (3) which read as follows: "which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlorotetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to assure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug."


1976—Par. (h). Pub. L. 94–295, §3(a)(1)(A), expanded definition of "device" to include implements, machines, implants, in vitro reagents, and other similar or related articles, added recognition in the National Formulary or the United States Pharmacopeia, or any supplement to the Formulary or Pharmacopeia, to the enumeration of conditions under which a device may qualify for inclusion under this chapter, and inserted requirements that a device be one which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Par. (n). Pub. L. 94–278 inserted "or advertising" after "labeling" wherever appearing.


1970—Par. (a)(2). Pub. L. 91–513, §701(g), struck out reference to sections 321, 331(i), 331(p), 331(q), 332, 333, 334, 337, 360, 360a, 372, 373, 374, and 375 of this title as they apply to depressant or stimulant drugs.

Par. (v). Pub. L. 91–513, §701(a), struck out par. (v) which defined "depressant or stimulant drug".

1968—Par. (a)(2). Pub. L. 90–639, §4(a), extended provisions to cover depressant and stimulant drugs, the containers thereof, and equipment used in manufacturing, compounding, or processing such drugs, to the Canal Zone.

Par. (p). Pub. L. 90–399, §102(a), (b), inserted "(except a new animal drug or an animal feed bearing or containing a new animal drug)" after "Any drug" in subpars. (1) and (2), respectively.

Par. (s)(5). Pub. L. 90–399, §102(c), added subpar. (5).

Par. (u). Pub. L. 90–399, §102(d), inserted reference to section 360b of this title.

Pars. (w), (x). Pub. L. 90–399, §102(e), added pars. (w) and (x).

1965—Par. (g). Pub. L. 89–74, §9(b), designated existing provisions as subpar. (1), redesignated cls. (1) to (4) thereof as (A) to (D), substituted "(A), (B), or (C)" for "(1), (2), or (3)" and added subpar. (2).

Par. (v). Pub. L. 89–74, §3(a), added par. (v).


Par. (p)(1). Pub. L. 87–781, §102(a)(1), inserted "and effectiveness" after "to evaluate the safety", and "and effective" after "as safe".

Par. (p)(2). Pub. L. 87–781, §102(a)(2), inserted "and effectiveness" after "safety".

1960—Par. (s). Pub. L. 86–618, §101(a), excluded color additives from definition of "food additive".

Par. (t). Pub. L. 86–618, §101(c), added par. (t). Former par. (t) redesignated (u).

Par. (u). Pub. L. 86–618, §101(b), redesignated par. (t) as (u) and inserted reference to section 376 of this title.

1958—Pars. (s), (t). Pub. L. 85–929 added pars. (s) and (t).

1954—Pars. (q), (r). Act July 22, 1954, added pars. (q) and (r).

Effective Date of 2004 Amendment
Pub. L. 108–282, title II, §203(d), Aug. 2, 2004, 118 Stat. 908, provided that: "The amendments made by this section [amending this section and sections 343 and 343–1 of this title] shall apply to any food that is labeled on or after January 1, 2006."

Effective Date of 1997 Amendment
Pub. L. 105–115, title V, §501, Nov. 21, 1997, 111 Stat. 2380, provided that: "Except as otherwise provided in this Act [see Short Title of 1997 Amendment note set out under section 301 of this title], this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307 [enacting section 355a of this title, amending this section and sections 331, 335a, 351, 352, 360, 360j, 360aa to 360cc, 360ee, 374, 379g, 381, and 382 of this title, section 45C of Title 26, Internal Revenue Code, section 156 of Title 35, Patents, and section 8126 of Title 38, Veterans' Benefits, repealing sections 356 and 357 of this title, and enacting provisions set out as notes under sections 351 and 355 of this title], shall take effect 90 days after the date of enactment of this Act [Nov. 21, 1997]."

Effective Date of 1990 Amendment
Amendment by Pub. L. 101–535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101–535, set out as a note under section 343 of this title.

Effective Date of 1976 Amendment

169
Amendment by Pub. L. 94–278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94–278, set out as a note under section 334 of this title.

**Effective Date of 1972 Amendment**

Amendment by Pub. L. 92–516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92–516, and regulations thereunder, see section 4 of Pub. L. 92–516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

**Effective Date of 1970 Amendment**


**Effective Date of 1968 Amendments; Transitional Provisions**


Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, except that in the case of a drug (other than one subject to section 360b(n) of this title) intended for use in animals other than man which, on Oct. 9, 1962, was commercially used or sold in the United States, was not a new drug as defined in par. (p) of this section then in force, and was not covered by an effective application under section 355 of this title, the words "effectiveness" and "effective" contained in par. (v) of this section not applicable to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day, see section 108(a), (b)(3) of Pub. L. 90–399, as amended, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

**Effective Date of 1965 Amendment**

Pub. L. 89–74, §11, July 15, 1965, 79 Stat. 235, provided that: "The foregoing provisions of this Act [see Short Title of 1965 Amendment note set out under section 301 of this title] shall take effect on the first day of the seventh calendar month [Feb. 1, 1966] following the month in which this Act is enacted [July 15, 1965]; except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title], to register their name, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such effective date, and (2) sections 201(v) and 511(g) of the Federal Food, Drug, and Cosmetic Act, as added by this act [par. (v) of this section and par. (g) of section 360a of this title], and the provisions of sections 8 [amending section 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure] and 10 [set out as a note under this section] shall take effect upon the date of enactment of this Act [July 15, 1965]."

**Effective Date of 1962 Amendment**

"(a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A [amending this section and sections 331, 332, 348, 351 to 353, 355, 357, 379e of this title, and enacting provisions set out as a note under section 355 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962].

"(b) The amendments made by sections 101, 103, 105, and 106 of this part A [amending sections 331, 332, 351, 352, 355, and 357 of this title] shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted [Oct. 1962].

"(c)(1) As used in this subsection, the term 'enactment date' means the date of enactment of this Act; and the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter].

"(2) An application filed pursuant to section 505(b) of the basic Act [section 355(b) of this title] which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act.

"(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection—

"(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act [par. (p) of this section, and secs. (b) and (d) of section 355 of this title], insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act [section 355(e) of this title], apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

"(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act [section 355(e) of this title], shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act [section 355 of this title]) until whichever of the following first occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act [section 355(e) of this title], other than clause (3) of the first sentence of such section 505(e) [section 355(e) of this title], withdrawing or suspending the approval of such application.

"(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force [par. (p) of this section], and (C) was not covered by an effective application under section 505 of that Act [section 355 of this title], the amendments to section 201(p) [par. (p) of this section] made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."
EFFECTIVE DATE OF 1960 AMENDMENT

EFFECTIVE DATE OF 1958 AMENDMENT
Amendment by Pub. L. 85–929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT
For effective date of amendment by act July 22, 1954, see section 5 of that act, set out as a note under section 342 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102–282
Amendment by Pub. L. 102–282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102–282, see section 7 of Pub. L. 102–282, set out as a note under section 335a of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

SAVINGS PROVISION

"(a) Prosecutions for any violation of law occurring prior to the effective date [see Effective Date of 1970 Amendment note above] of section 701 [repealing section 360a of this title, and amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare] shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on the date of enactment of this Act [Oct. 27, 1970] shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act [par. (v) of this section], such drug shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has
been made prior to the date of enactment of this Act which is not listed in section 202 [section 812 of this title] within schedules I through V shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

"(d) Notwithstanding subsection (a) of this section or section 1103 [of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title], section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III [subchapter I or subchapter II of chapter 13 of this title] without regard to the terms of any sentence imposed on such individual under such law."

**TRANSFER OF FUNCTIONS**

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.


Functions of Secretary of Health, Education, and Welfare [now Health and Human Services] under Drug Abuse Control Amendments of 1965 [see Short Title of 1965 Amendment note set out under section 301 of this title] transferred to Attorney General except function of regulating counterfeiting of those drugs which are not "depressant or stimulant" drugs, see section 2 of Reorg. Plan No. 1 of 1968, set out in the Appendix to Title 5, Government Organization and Employees.


Food and Drug Administration in Department of Agriculture and its functions, except those functions relating to administration of Insecticide Act of 1910 and Naval Stores Act, transferred to Federal Security Agency, to be administered under direction and supervision of Federal Security Administrator, by Reorg. Plan No. IV of 1940, set out in the Appendix to Title 5.

**REGULATION OF TOBACCO**

Pub. L. 105–115, title IV, §422, Nov. 21, 1997, 111 Stat. 2380, provided that: "Nothing in this Act [see Short Title of 1997 Amendment note set out under section 301 of this title] or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] as in effect on the day before the date of the enactment of this Act [Nov. 21, 1997]."

**CONGRESSIONAL FINDINGS RELATING TO PUB. L. 103–417**

"(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

"(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

"(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

"(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

"(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

"(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

"(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

"(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

"(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

"(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

"(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

"(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

"(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

"(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

"(B) the industry consistently projects a positive trade balance; and

"(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;
“(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

“(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

“(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

“(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.”

**Dissemination of Information Regarding the Dangers of Drug Abuse**

*Pub. L. 90–639, §5, Oct. 24, 1968, 82 Stat. 1362*, provided that: “It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse.”

**Congressional Findings and Declaration of Policy**

*Pub. L. 89–74, §2, July 15, 1965, 79 Stat. 226*, provided that: "The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act [see Short Title of 1965 Amendment note set out under section 301 of this title], would discriminate against and adversely affect interstate commerce in such drugs."

**Effect of Drug Abuse Control Amendments of 1965 on State Laws**


"(a) Nothing in this Act [enacting section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title] shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

"(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together."
"(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment."

**Effect of Drug Amendments of 1962 on State Laws**

Pub. L. 87–781, title II, §202, Oct. 10, 1962, 76 Stat. 793, provided that: "Nothing in the amendments made by this Act [enacting sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title] to the Federal Food, Drug, and Cosmetic Act [this chapter] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

**Definitions**

Pub. L. 105–115, §2, Nov. 21, 1997, 111 Stat. 2297, provided that: "In this Act [see Short Title of 1997 Amendment note set out under section 301 of this title], the terms 'drug', 'device', 'food', and 'dietary supplement' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

1 So in original. Probably should be paragraph "(v)."

2 So in original. Provision probably should be set flush with subpar. (B).

§321a. "Butter" defined

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

(Mar. 4, 1923, ch. 268, 42 Stat. 1500.)

**References in Text**

The Food and Drug Act of June 30, 1906, referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, §1002(a), formerly §902(a), 52 Stat. 1059; renumbered §1002(a), Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784, and is covered by this chapter.

**Codification**

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to section 6 of this title. Section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

§321b. "Package" defined

The word "package" where it occurs the second and last time in the act entitled "An act to amend section 8 of an act entitled, 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,' " approved March 3, 1913,
shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

(July 24, 1919, ch. 26, 41 Stat. 271.)

REFERENCES IN TEXT

An act approved March 3, 1913, referred to in text, is act Mar. 3, 1913, ch. 117, 37 Stat. 732, which amended section 10 of this title. For complete classification of this Act to the Code, see Tables.

"An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes", referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, §1002(a), formerly §902(a), 52 Stat. 1059; renumbered §1002(a), Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784, and is covered by this chapter.

CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to the last sentence of paragraph third of section 10 of this title. Section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

§321c. Nonfat dry milk; "milk" defined

For the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938, (ch. 675, sec. 1, 52 Stat. 1040) [21 U.S.C. 301 et seq.] nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows.


REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (§301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, substituted "nonfat dry milk" for "nonfat dry milk solids or defatted milk solids".

§321d. Market names for catfish and ginseng

(a) Catfish labeling

177
(1) In general
    Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—
    (A) the term "catfish" may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and
    (B) only labeling or advertising for fish classified within that family may include the term "catfish".

(2) Omitted

(b) Ginseng labeling

(1) In general
    Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—
    (A) the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and
    (B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term "ginseng".

(2) Omitted


REFERENCES IN TEXT
The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (b)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Farm Security and Rural Investment Act of 2002, and not as part of Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§331. Prohibited acts
The following acts and the causing thereof are prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb–3 of this title.
(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bb–3, 373, 374(a), 379a, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc–1(i), 360e(f), 360i, 360bb–3, 379aa, 379aa–1, 387i, or 387l of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.


(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes
written request for information as to such drug, true and correct copies of all printed matter
which is required to be included in any package in which that drug is distributed or sold, or such
other printed matter as is approved by the Secretary. Nothing in this paragraph shall be
construed to exempt any person from any labeling requirement imposed by or under other
provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to
provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the
failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

(q)(1) The failure or refusal—
(A) to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g,
387h, or 387o of this title;
(B) to furnish any notification or other material or information required by or under section
360i, 360j(g), 387d, 387i, or 387t of this title; or
(C) to comply with a requirement under section 360l or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is
required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device, drug, or tobacco product in violation of an order under section
334(g) of this title or the removal or alteration of any mark or label required by the order to
identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the
failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the
records required by section 350a(b)(4) of this title, or the failure to meet the requirements
prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase,
trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in
violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell,
purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section
353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or
the failure to otherwise comply with the requirements of section 353(d) of this title, the
distribution of drugs in violation of section 353(e) of this title, failure to comply with the
requirements under section 360eee–1 of this title, the failure to comply with the requirements
under section 360eee–3 of this title, as applicable, or the failure to otherwise comply with the
requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or
orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary
supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis,
record, or report required or requested under section 381(d)(3) of this title; the failure to submit
a certificate of analysis as required under such section; the failure to maintain records or to
submit records or reports as required by such section; the release into interstate commerce of
any article or portion thereof imported into the United States under such section or any finished
product made from such article or portion, except for export in accordance with section 381(e)
or 382 of this title, or with section 262(h) of title 42; or the failure to so export or to destroy such
an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this
title or the failure or refusal to provide data or information requested by the Secretary under
paragraph (3) of such section.

(y) In the case of a drug, device, or food—
(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted.

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa–1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa–1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353c-1 of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under
such section 262 of title 42, and before any substantial clinical investigations involving the
drug or the biological product have been instituted;
(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and
comment, approving the use of such drug or such biological product in the food;
(3) the use of the drug or the biological product in the food is to enhance the safety of the
food to which the drug or the biological product is added or applied and not to have
independent biological or therapeutic effects on humans, and the use is in conformity with—
(A) a regulation issued under section 348 of this title prescribing conditions of safe use in
food;
(B) a regulation listing or affirming conditions under which the use of the drug or the
biological product in food is generally recognized as safe;
(C) the conditions of use identified in a notification to the Secretary of a claim of
exemption from the premarket approval requirements for food additives based on the
notifier's determination that the use of the drug or the biological product in food is generally
recognized as safe, provided that the Secretary has not questioned the general recognition
of safety determination in a letter to the notifier;
(D) a food contact substance notification that is effective under section 348(h) of this
title; or
(E) such drug or biological product had been marketed for smoking cessation prior to
September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of
this title.
(nn) The falsification of a report or notification required under section 350f(d) of this title.
(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section
333(f) of this title.
(pp) The introduction or delivery for introduction into interstate commerce of a tobacco
product in violation of section 387k of this title.
(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority
using any mark, stamp (including tax stamp), tag, label, or other identification device upon any
tobacco product or container or labeling thereof so as to render such tobacco product a
counterfeit tobacco product.
(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing
any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the
trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of
any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a
counterfeit tobacco product.
(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or
the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.
(rr) The charitable distribution of tobacco products.
(ss) The failure of a manufacturer or distributor to notify the Attorney General and the
Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.
(tt) Making any express or implied statement or representation directed to consumers with
respect to a tobacco product, in a label or labeling or through the media or advertising, that
either conveys, or misleads or would mislead consumers into believing, that—
(1) the product is approved by the Food and Drug Administration;
(2) the Food and Drug Administration deems the product to be safe for use by consumers;
The product is endorsed by the Food and Drug Administration for use by consumers; or
(A) its regulation or inspection by the Food and Drug Administration; or
(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350h of this title.

(wv) The failure to comply with section 350l of this title.

(xx) The refusal or failure to follow an order under section 350i of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

(aaa) The failure to register in accordance with section 381(s) of this title.

(bbb) The failure to notify the Secretary in violation of section 360bbb–7 of this title.

(ccc)(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 353b of this title.

(2) With respect to a drug to be compounded pursuant to section 353a or 353b of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—
(A) the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and
(B) the term "rinse-off cosmetic" includes toothpaste.

REFERENCES IN TEXT

Section 2223 of this title, referred to in par. (e), was in the original "section 204 of the FDA Food Safety Modernization Act", meaning section 204 of Pub. L. 111–353, which enacted section 2223 of this title and amended this section and section 381 of this title.

Section 353c of this title, referred to in par. (kk), was in the original a reference to section 503B of act June 25, 1938, and was translated as if it referred to section 503C of that Act, to reflect the probable intent of Congress and the renumbering of section 503B as 503C by Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 587, and its transfer to section 353c of this title. A new section 503B, which was enacted by section 102(a)(2) of Pub. L. 113–54, is classified to section 353b of this title and does not relate to television advertisements.

CONSTITUTIONALITY

For information regarding constitutionality of certain provisions of section 301 of act June 25, 1938, see Congressional Research Service, The Constitution of the United States of America: Analysis and Interpretation, Appendix 1, Acts of Congress Held Unconstitutional in Whole or in Part by the Supreme Court of the United States.

AMENDMENTS


2013—Par. (t). Pub. L. 113–54, §206(a), struck out "or" after "the requirements of section 353(d) of this title," and inserted ", failure to comply with the requirements under section 360eee–1 of this title, the failure to comply with the requirements under section 360eee–3 of this title, as applicable," after "in violation of section 353(e) of this title".


Par. (e). Pub. L. 111–353, §§204(j)(1), 211(c), substituted "350f(j)" for "350f(g)" and inserted before period at end "; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm)"


Par. (vv). Pub. L. 111–353, §105(c), added par. (vv).


Par. (e). Pub. L. 111–31, §103(b)(4)(B), which directed substitution of "379aa–1, 387i, or 387t of this title or the refusal to permit access to" for "or 379aa–1 of this title or the refusal to permit access to", was executed by making the substitution for "or 379aa–1 of this title, or the refusal to permit access to", to reflect the probable intent of Congress.

Pub. L. 111–31, §103(b)(4)(A), struck out period after "360ccc–1(i)"

Pars. (g), (h). Pub. L. 111–31, §103(b)(5), (6), inserted "tobacco product," after "device,"

Par. (j). Pub. L. 111–31, §103(b)(7), struck out period after "360ccc–2" and substituted "379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b)" for "379, or 379e"


Par. (p). Pub. L. 111–31, §103(b)(9), added par. (p) and struck out former par. (p) which read as follows: "The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title."

Par. (q)(1). Pub. L. 111–31, §103(b)(10), added subpar. (1) and struck out former subpar. (1) which read as follows: "The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title, or (C) comply with a requirement under section 360l of this title."

Par. (q)(2). Pub. L. 111–31, §103(b)(11), substituted "device or tobacco product," for "device,"

Par. (r). Pub. L. 111–31, §103(b)(12), inserted "or tobacco product" after "device" in two places.

Pars. (oo) to (tt). Pub. L. 111–31, §103(b)(13), added pars. (oo) to (tt).

185
2007—Par. (e). Pub. L. 110–85, §1005(d)(1), substituted "350c, 350f(g)," for "350c," and "350c(b), 350f" for "350c(b)".


Pars. (mm), (nn). Pub. L. 110–85, §1005(d)(2), added pars. (mm) and (nn).

2006—Par. (e). Pub. L. 109–462, §3(b), substituted "374(a), 379aa, or 379aa–1" for "374(a), or 379aa" and "360bbb–3, 379aa, or 379aa–1" for "360bbb–3, or 379aa".

Pub. L. 109–462, §2(c), substituted ", 374(a), or 379aa" for ", or 374(a)" and ", 360bbb–3, or 379aa" for ", or 360bbb–3".


2004—Par. (e). Pub. L. 108–282, §102(b)(5)(C), which directed the substitution of "360b(a)(4)(C), 360b (j), (l) or (m), 360ccc–1(i)." for "360b(a)(4)(C), 360b(j), (l) or (m)" was executed by making the substitution for "360b(a)(4)(C), 360b(j), (l), or (m)", to reflect the probable intent of Congress.


Par. (gg). Pub. L. 108–214 amended par. (gg) generally. Prior to amendment, text read as follows: "The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report."

2003—Par. (d). Pub. L. 108–136 substituted "section 344, 355, or 360bbb–3" for "section 344 or 355".

Par. (e). Pub. L. 108–136 inserted "360bbb–3," after "350c, 354," and substituted "360i, or 360bbb–3" for "or 360i".


2002—Par. (e). Pub. L. 107–188, §306(c)(1), substituted "by section 350a, 350c, 354, 373, or 374(a) of this title" for "by section 350a, 354, or 373 of this title" and "under section 350a, 350c(b)" for "under section 350a".


Par. (w). Pub. L. 107–188, §322(b), amended par. (w) generally. Prior to amendment, par. (w) read as follows: "The making of a knowingly false statement in any record or report required or requested under subparagraph (A) or (B) of section 381(d)(3) of this title, the failure to submit or maintain records as required by sections 381(d)(3)(A) and 381(d)(3)(B) of this title, the release into interstate commerce of any article imported into the United States under section 381(d)(3)
of this title or any finished product made from such article (except for export in accordance with section 381(e) or 382 of this title or section 262(h) of title 42), or the failure to export or destroy any component, part or accessory not incorporated into a drug, biological product or device that will be exported in accordance with section 381(e) or 382 of this title or section 262(h) of title 42."


1997—Par. (e). Pub. L. 105–115, §125(b)(2)(B), struck out "357(d) or (g)," after "355(i) or (k),".
Par. (l). Pub. L. 105–115, §421, struck out par. (l) which read as follows: "The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360j(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section."

1996—Par. (e). Pub. L. 104–250 inserted ", 354," before "or 373 of this title" and "354," before "355(i) or (k)".
Par. (j). Pub. L. 104–170 inserted before period at end of first sentence "; or the violating of section 346a(i)(2) of this title or any regulation issued under that section."
Paras. (u) to (w). Pub. L. 104–134 redesignated par. (u) relating to introduction into interstate commerce of unsafe dietary supplement as (v) and added par. (w).

1994—Par. (e). Pub. L. 103–396, §2(b)(1)(A), substituted "357(d) or (g), 360b(a)(4)(C)," for "357(d) or (g),".
Par. (u). Pub. L. 103–417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.
Pub. L. 103–396, §2(b)(1)(B), added par. (u) relating to failure to comply with regulations or orders of Secretary.

1993—Par. (j). Pub. L. 103–80, §3(c)(1), substituted "379, or 379e" for "379, or 379e".

Par. (s). Pub. L. 103–80, §3(c)(2), substituted "350a(e)" for "350a(d)".


1990—Par. (e). Pub. L. 101–502 substituted "or (k)" for "or (j)".

Par. (j). Pub. L. 101–508 inserted at end "This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee."


1986—Par. (s). Pub. L. 99–570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: "The failure to provide the notice required by section 350a(b) or 350a(c), the failure to make the reports required by section 350a(d)(1)(B), or the failure to meet the requirements prescribed under section 350a(d)(2)."


Par. (s). Pub. L. 96–359, §5(a), added par. (s).

1976—Par. (e). Pub. L. 94–295, §3(b)(2), inserted references to sections 360e(f) and 360i of this title.

Par. (j). Pub. L. 94–295, §3(b)(3), inserted references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of this title.

Par. (l). Pub. L. 94–295, §3(b)(4), substituted "drug or device" for "drug" wherever appearing, and inserted references to sections 360e and 360j(g) of this title.

Par. (p). Pub. L. 94–295, §4(b)(1), substituted "section 360(j) or 360(k) of this title," for "section 360(j) of this title,"


1972—Par. (p). Pub. L. 92–387 added failure to provide information required by section 360(j) of this title, and failure to provide notice required by section 360(j)(2) of this title as prohibited acts.

1970—Par. (q). Pub. L. 91–513 struck out par. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.
1968—Par. (e). Pub. L. 90–399, §103(1), struck out "or" before "357(d) or (g)" and inserted ", or 360b(j), (l), or (m)" after "357(d) or (g)". Amendment striking out "or" was executed as described, notwithstanding directory language that "or" before "357," be stricken out, to reflect the probable intent of Congress.


Par. (q). Pub. L. 90–639 divided cl. (3), which referred simply to possession in violation of section 360a(c) of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360a(c)(1) of this title and possession in violation of section 360a(c)(2) of this title.

1965—Par. (i). Pub. L. 89–74, §9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).


1962—Par. (e). Pub. L. 87–781, §§103(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 507(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.

Par. (l). Pub. L. 87–781, §104(e)(1), inserted "approval of" before "an application", and substituted "in effect" for "effective".


1960—Par. (i). Pub. L. 86–618, §105(a), struck out references to sections 346(b), 354, and 364 of this title and inserted reference to section 376 of this title.


1948—Par. (k). Act June 24, 1948, inserted "(whether or not the first sale)" so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended coverage of subsection to acts which result in adulteration.


**Effective Date of 2015 Amendment**

Pub. L. 114–114, §2(b), Dec. 28, 2015, 129 Stat. 3129, provided that:

"(1) In general.—The amendment made by subsection (a) [amending this section] applies—
“(A) with respect to manufacturing, beginning on July 1, 2017, and with respect to introduction or delivery for introduction into interstate commerce, beginning on July 1, 2018; and

“(B) notwithstanding subparagraph (A), in the case of a rinse-off cosmetic that is a nonprescription drug, with respect to manufacturing, beginning on July 1, 2018, and with respect to the introduction or delivery for introduction into interstate commerce, beginning on July 1, 2019.

“(2) Nonprescription drug.—For purposes of this subsection, the term 'nonprescription drug' means a drug not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1))."

**Effective Date of 2011 Amendment**

Amendment by section 103(e) of Pub. L. 111–353 effective 18 months after Jan. 4, 2011, and applicable to a small business (as defined in the regulations promulgated under section 350g(n) of this title) beginning on the date that is 6 months after the effective date of such regulations and to a very small business (as defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations, see section 103(i) of Pub. L. 111–353, set out as an Effective Date note under section 350g of this title.

Pub. L. 111–353, title III, §301(d), Jan. 4, 2011, 124 Stat. 3955, provided that: "The amendments made by this section [enacting section 384a of this title and amending this section and section 381 of this title] shall take effect 2 years after the date of enactment of this Act [Jan. 4, 2011]."

**Effective Date of 2007 Amendment**

Pub. L. 110–85, title IX, §909, Sept. 27, 2007, 121 Stat. 950, provided that:

"(a) Effective Date.—This subtitle [subtitle A (§§901–909) of title IX of Pub. L. 110–85, enacting sections 353b and 355–1 of this title, amending this section, sections 333, 352, and 355 of this title, and section 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 352, 355, and 355a of this title] takes effect 180 days after the date of enactment of this Act [Sept. 27, 2007].

"(b) Drugs Deemed to Have Risk Evaluation and Mitigation Strategies.—

"(1) In general.—A drug that was approved before the effective date of this Act [probably means "this subtitle", see above] is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355–1] (as added by section 901) (referred to in this section as the 'Act') if there are in effect on the effective date of this Act elements to assure safe use—

"(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

"(B) otherwise agreed to by the applicant and the Secretary for such drug.

"(2) Elements of strategy; enforcement.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

"(A) is deemed to consist of the timetable required under section 505–1(d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and
"(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act [21 U.S.C. 333(f)(4), 352(y), (z)] (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505–1.

"(3) Submission.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary."

**Effective Date of 2006 Amendment**
Amendment by section 2(c) of Pub. L. 109–462 effective 1 year after Dec. 22, 2006, see section 2(e)(1) of Pub. L. 109–462, set out as a note under section 352 of this title.

Amendment by section 3(b) of Pub. L. 109–462 effective 1 year after Dec. 22, 2006, see section 3(d)(1) of Pub. L. 109–462, set out as a note under section 343 of this title.

**Effective Date of 2005 Amendment**

**Effective Date of 2002 Amendment**

**Effective and Termination Dates of 1997 Amendment**

Amendment by section 401(b) of Pub. L. 105–115 effective 1 year after Nov. 21, 1997, or upon Secretary's issuance of final regulations pursuant to section 401(c) of Pub. L. 105–115, whichever is sooner, and ceases to be effective Sept. 30, 2006, see section 401(d), (e) of Pub. L. 105–115, set out as an Effective and Termination Dates note under former section 360aaa of this title.
**Effective Date of 1994 Amendment**
Amendment by Pub. L. 103–396 effective upon adoption of final regulations under section 2(c) of Pub. L. 103–396, set out as a Regulations note under section 360b of this title, see section 2(d) of Pub. L. 103–396, set out as a note under section 360b of this title.

**Effective Date of 1990 Amendment**

**Effective Date of 1988 Amendment**
Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

**Effective Date of 1972 Amendment**

**Effective Date of 1970 Amendment**

**Effective Date of 1968 Amendments**
Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

**Effective Date of 1965 Amendment**

**Effective Date of 1962 Amendment**
Amendment by sections 103(c) and 106(c) of Pub. L. 87–781 effective on first day of seventh calendar month following Oct. 1962, and amendment by section 104(e)(1) of Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

Pub. L. 87–781, title I, §114(b), Oct. 10, 1962, 76 Stat. 791, provided that: "This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962]."

**Effective Date of 1960 Amendment**
EFFECTIVE DATE OF 1958 AMENDMENT
Amendment by Pub. L. 85–929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT
Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of that act, set out as an Effective Date note under section 347 of this title.

REGULATIONS
Pub. L. 113–54, title I, §104, Nov. 27, 2013, 127 Stat. 597, provided that: "In promulgating any regulations to implement this title [enacting subpart 9 of part C of subchapter VII of this chapter and sections 353a–1 and 353b of this title, amending this section and sections 352, 353a, 352b, and 353c of this title, and enacting provisions set out as notes under section 301 of this title] (and the amendments made by this title), the Secretary of Health and Human Services shall—

"(1) issue a notice of proposed rulemaking that includes the proposed regulation;

"(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and

"(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation."

Secretary of Health and Human Services to promulgate regulations to implement amendments made by section 401 of Pub. L. 105–115 not later than 1 year after Nov. 21, 1997, see section 401(c) of Pub. L. 105–115, set out as a note under section 360aaa of this title.

SAVINGS PROVISIONS
Pub. L. 113–54, title II, §208, Nov. 27, 2013, 127 Stat. 640, provided that: "Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 204(a) [amending section 353 of this title] and by section 206(a) [amending this section], nothing in this title [enacting part H of subchapter V of this chapter, amending this section and sections 333, 352, 353, and 360ee–1 of this title, and enacting provisions set out as notes under sections 301, 333, and 353 of this title] (including the amendments made by this title) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under any other provision of such Act [21 U.S.C. 301 et seq.] or the Public Health Service Act (42 U.S.C. 201 et seq.)..

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

CONSTRUCTION OF 2015 AMENDMENT
Pub. L. 114–114, §2(d), Dec. 28, 2015, 129 Stat. 3130, provided that: "Nothing in this Act [amending this section and enacting provisions set out as notes under this section and section 301 of this title] (or the amendments made by this Act) shall be construed to apply with respect
to drugs that are not also cosmetics (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321))."

**CONSTRUCTION OF 2011 AMENDMENT**

Nothing in amendments by sections 103(e), 105(c), 106(d), 204(j)(1), 211(b), (c), and 301(b) of Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, see section 2206 of this title.

Nothing in amendments by Pub. L. 111–353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

**CONSTRUCTION OF 2009 AMENDMENTS**

Pub. L. 111–31, div. A, title I, §103(p), June 22, 2009, 123 Stat. 1838, provided that: "Nothing in this section [amending this section and sections 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacting provisions set out as notes under sections 333 and 387c of this title] is intended or shall be construed to expand, contract, or otherwise modify or amend the existing limitations on State government authority over tribal restricted fee or trust lands."

**CONSTRUCTION OF 2002 AMENDMENTS**

Pub. L. 107–188, title III, §315, June 12, 2002, 116 Stat. 675, provided that: "Nothing in this title [enacting sections 350c, 350d, 398, 399, and 679c of this title, sections 3353, 3354, 8319, and 8320 of Title 7, Agriculture, and section 247b–20 of Title 42, The Public Health and Welfare, amending this section, sections 334, 335a, 342, 343, 360, 372, 374, and 381 of this title, and section 43 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under this section and sections 341, 350c, 350d, and 381 of this title], or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations."

**TRANSFER OF FUNCTIONS**

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**PREEMPTION OF STATE LAWS**

Pub. L. 114–114, §2(c), Dec. 28, 2015, 129 Stat. 3129, provided that: "No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads (as defined in section 301(ddd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) that are not identical to the restrictions under such section 301(ddd) that have begun to apply under subsection (b) [set out as a note above]."

1 See References in Text note below.

2 So in original.
§333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(1) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative’s employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase,
or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 384(b) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 351 of this title and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.

(8) Notwithstanding subsection (a), any person who violates section 331(i)(3) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title 18, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and
address of, the manufacturer of the color additive, to the effect that such color additive was from
a batch certified in accordance with the applicable regulations promulgated by the Secretary
under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to
comply with section 352(f) of this title in respect to an article received in interstate commerce to
which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered
delivery was made in good faith and the labeling at the time thereof contained the same
directions for use and warning statements as were contained in the labeling at the time of such
receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted
in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing
involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3)
of this title if the person doing the act or causing it to be done acted in good faith and had no
reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food
No person shall be subject to the penalties of subsection (a)(1) of this section for a violation
of section 331 of this title involving misbranded food if the violation exists solely because the
food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with
intent to distribute, human growth hormone for any use in humans other than the treatment of a
disease or other recognized medical condition, where such use has been authorized by the
Secretary of Health and Human Services under section 355 of this title and pursuant to the
order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such
fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an
individual under 18 years of age is punishable by not more than 10 years imprisonment, such
fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be
considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the
purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].

(4) As used in this subsection the term “human growth hormone” means somatrem,
somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by
this subsection.

(f) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this
chapter which relates to devices shall be liable to the United States for a civil penalty in an
amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all
such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a
person accredited under paragraph (2) of section 374(g) of this title who is substantially not in
compliance with the standards of accreditation under such section, or who poses a threat to
public health or fails to act in a manner that is consistent with the purposes of such section, shall
be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360i(f) of this
title unless such violation constitutes (I) a significant or knowing departure from such
requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or 360i(g) of this
title (only with respect to correction reports) if such person demonstrates substantial
compliance with such section, or
(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 342(a)(2)(B) of this title or any person who does not comply with a recall order under section 350l of this title shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 334 of this title or the injunction authorities of section 332 of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 346a(g)(2)(B) of this title. The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.

(3)(A) Any person who violates section 331(jj) of this title shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 331(jj) of this title is not corrected within the 30-day period following notification under section 282(j)(5)(C)(ii) of title 42, the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.

(4)(A) Any responsible person (as such term is used in section 355–1 of this title) that violates a requirement of section 355(o), 355(p), or 355–1 of this title shall be subject to a civil monetary penalty of—

(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 355(o), 355(p), or 355–1 of this title for which the responsible person is subject to such civil penalty.

(5)(A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed, under such order of the Secretary’s proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas.
requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 387f(d) of this title at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer’s request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) Civil Monetary Penalties for Violation of Tobacco Product Requirements.—

(A) In general.—Subject to subparagraph (B), any person who violates a requirement of this chapter which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) Enhanced penalties.—
(i) Any person who intentionally violates a requirement of section 387b(5), 387b(6), 387d, 387h(c), or 387k(a) of this title, shall be subject to a civil monetary penalty of—
(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or
(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of section 387k(g)(2)(C)(ii) or 387k(i)(1) of this title, shall be subject to a civil monetary penalty of—
(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or
(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g) Violations regarding direct-to-consumer advertising

(1) With respect to a person who is a holder of an approved application under section 355 of this title for a drug subject to section 353(b) of this title or under section 262 of title 42, any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this chapter (including the civil penalty in subsection (f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence
that relates to the matter under investigation, including information pertaining to the factors
described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall
take into account the nature, circumstances, extent, and gravity of the violation or violations,
including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review
under section 379h–1 of this title.

(B) Whether the person submitted the advertisement for review if required under section
353c of this title.

(C) Whether, after submission of the advertisement as described in subparagraph (A) or
(B), the person disseminated or caused another party to disseminate the advertisement
before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to
the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written
notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory,
and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be
created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be
created has been assessed a civil penalty under this provision within the previous 1-year
period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under
paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or
caused another party to disseminate such advertisement after incorporating each comment
received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an
advertisement submitted to the Secretary based on new information or changed circumstances,
so long as the Secretary provides written notice to the person of the new views of the Secretary
on the advertisement and provides a reasonable time for modification or correction of the
advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil
penalty which may be assessed under paragraph (1). The amount of such penalty, when finally
determined, or the amount charged upon in compromise, may be deducted from any sums
owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to
the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty,
may file a petition for de novo judicial review of such order with the United States Court of
Appeals for the District of Columbia Circuit or for any other circuit in which such person resides
or transacts business. Such a petition may only be filed within the 60-day period beginning on
the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

(A) after the order making the assessment becomes final, and if such person does not file a
petition for judicial review of the order in accordance with paragraph (6), or
(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.


REFERENCES IN TEXT


Section 282(j)(5)(C)(ii) of title 42, referred to in subsec. (f)(3)(B), was in the original "section 402(j)(5)(C)(ii)", and was translated as meaning section 402(j)(5)(C)(ii) of the Public Health Service Act to reflect the probable intent of Congress because there is no subsec. (j) of section 402 of the Federal Food, Drug, and Cosmetic Act and section 402(j)(5)(C)(ii) of the Public Health Service Act relates to notification of noncompliance with clinical trial information requirements.

Section 353c of this title, referred to in subsec. (g)(3)(B), was in the original a reference to section 503B of act June 25, 1938, and was translated as if it referred to section 503C of that Act, to reflect the probable intent of Congress and the renumbering of section 503B as 503C by Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587, and its transfer to section 353c of this title. A new section 503B, which was enacted by section 102(a)(2) of Pub. L. 113–54, is classified to section 353b of this title and does not relate to television advertisements.

AMENDMENTS


2009—Subsec. (f)(5)(A). Pub. L. 111–31, §103(c)(1)(A), (B), substituted "paragraph (1), (2), (3), (4), or (9)" for "paragraph (1), (2), (3), or (4)", "shall be assessed, or a no-tobacco-sale order may be imposed," for "shall be assessed", and "assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed," for "assessed a civil penalty".

Subsec. (f)(5)(B). Pub. L. 111–31, §103(c)(1)(C), inserted "or the period to be covered by a no-tobacco-sale order," after "penalty," and inserted at end "A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order."

Subsec. (f)(5)(C). Pub. L. 111–31, §103(c)(1)(A), substituted "paragraph (1), (2), (3), (4), or (9)" for "paragraph (1), (2), (3), or (4)".


Subsec. (f)(6). Pub. L. 111–31, §103(c)(2), inserted "or the imposition of a no-tobacco-sale order" after "penalty" in two places and substituted "issued, or on which the no-tobacco-sale order was imposed, as the case may be." for "issued."

Subsec. (f)(8), (9). Pub. L. 111–31, §103(c)(3), added pars. (8) and (9).


Subsec. (f)(1)(B)(ii). Pub. L. 110–85, §226(b)(2), substituted "360i(g)" for "360i(f)".


Subsec. (f)(5)(A), (C). Pub. L. 110–85, §902(b)(2), substituted "paragraph (1), (2), (3), or (4)" for "paragraph (1), (2), or (3)".

Pub. L. 110–85, §801(b)(2)(D), substituted "paragraph (1), (2), or (3)" for "paragraph (1) or (2)".

Subsec. (f)(6). Pub. L. 110–85, §801(b)(2)(A), (E), redesignated par. (4) as (6) and substituted "paragraph (5)(A)" for "paragraph (3)(A)".

Subsec. (f)(7). Pub. L. 110–85, §801(b)(2)(A), (F), redesignated par. (5) as (7) and substituted "paragraph (6)" for "paragraph (4)" wherever appearing.

Pub. L. 110–85, §226(b)(1), redesignated subsec. (g) as (f).

2003—Subsec. (b)(6). Pub. L. 108–173, which directed amendment of subsec. (a)(6) by substituting "prescription drug under section 384(b)" for "covered product pursuant to section 384(a)", was executed by making the substitution in subsec. (b)(6), to reflect the probable intent of Congress.

2002—Subsec. (g)(1)(A). Pub. L. 107–250 inserted at end "For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices."


Subsec. (g)(3). Pub. L. 104–170, §407(1), (3), redesignated par. (2) as (3) and substituted "paragraph (1) or (2)" for "paragraph (1)" in subpars. (A) and (C). Former par. (3) redesignated (4).

Subsec. (g)(4). Pub. L. 104–170, §407(1), (4), redesignated par. (3) as (4) and substituted "paragraph (3)(A)" for "paragraph (2)(A)". Former par. (4) redesignated (5).

Subsec. (g)(5). Pub. L. 104–170, §407(1), (5), redesignated par. (4) as (5) and substituted "paragraph (4)" for "paragraph (3)" wherever appearing.


1993—Subsecs. (e) to (g). Pub. L. 103–80, which directed the amendment of this section by redesignating the second subsec. (e) and subsec. (f) as subsecs. (f) and (g), respectively, could only be executed by designating subsec. (f) as (g) because this section did not contain a second subsec. (e) subsequent to amendment of Pub. L. 101–647 by Pub. L. 103–322. See 1990 and 1994 amendment notes for subsec. (e) under this section.

1992—Subsec. (b)(1). Pub. L. 102–353, §3(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title because of an importation of a drug in violation of section 381(d)(1) of this title, because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, or the distribution of drugs in violation of section 353(e)(2)(A) of this title shall be imprisoned for not more than 10 years or fined not more than $250,000, or both."

Subsec. (b)(4)(A). Pub. L. 102–353, §3(b)(1), substituted "the institution of a criminal proceeding against," for "the arrest and conviction of".

Subsec. (b)(4)(B)(i). Pub. L. 102–353, §3(b)(1), (2), substituted "before the institution of a criminal proceeding against" for "before the arrest of" and "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".
Subsec. (b)(5). Pub. L. 102–353, §3(b)(3), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (c). Pub. L. 102–353, §3(b)(4), substituted "subsection (a)(1) of this section" for "subsection (a) of this section".

Subsec. (d). Pub. L. 102–353, §3(b)(4), (5), substituted "subsection (a)(1) of this section" for "subsection (a) of this section" and struck out ", and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead" after "advertising".

1990—Subsec. (e). Pub. L. 101–647, as amended by Pub. L. 103–322, amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows:

"(e)(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

"(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both."


1988—Subsecs. (a), (b). Pub. L. 100–293 designated existing subsecs. (a) and (b) as pars. (1) and (2) of subsec. (a), substituted "paragraph (1)" for "subsection (a)" in par. (2), and added subsec. (b).


1970—Subsec. (a). Pub. L. 91–513 struck out reference to subsec. (b) and transferred to subsec. (b) provisions covering second offenses and offenses committed with intent to defraud or mislead.

Subsec. (b). Pub. L. 91–513 inserted provisions covering second offenses and offenses committed with intent to defraud or mislead formerly set out in subsec. (a) and struck out provisions covering violations involving depressant and stimulant drugs. See section 801 et seq. of this title.

1968—Subsecs. (a), (b). Pub. L. 90–639 made a general revision in the penalties prescribed for offenses involving depressant or stimulant drugs, set a fine of not to exceed $10,000 or imprisonment of not more than 5 years for offenses involving the unlawful manufacturing of, sale, or disposal of, or possession with intent to sell, a depressant or stimulant drug or involving counterfeit depressant or stimulant drugs, stiffened the penalties for unlawful sales or other disposals by persons over 18 to persons under 21, and set new penalties for possession of a depressant or stimulant drug for purposes other than sale or other disposal.

1965—Subsec. (a). Pub. L. 89–74, §7(a), inserted proviso limiting the penalties for depressant or stimulant drug violations to two years imprisonment or $5,000 fine or both for first offense and to two years imprisonment or $15,000 fine or both for subsequent offenses.
Subsec. (b). Pub. L. 89–74, §7(b), inserted parenthetical exception provision.

Subsec. (c)(5). Pub. L. 89–74, §9(d), added cl. (5).

1960—Subsec. (c)(3). Pub. L. 86–618 substituted "a color additive" for "a coal-tar color", "the color additive" for "the coal-tar color" and "such color additive was" for "such color was".


**Effective Date of 2013 Amendment**

Pub. L. 113–54, title II, §207(b), Nov. 27, 2013, 127 Stat. 640, provided that: "The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2015."

**Effective Date of 2009 Amendment**


"(3) General effective date.—The amendments made by paragraphs (2) [amending this section], (3) [amending this section], and (4) [no par. (4) has been enacted] of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection [set out as a Guidance note below]."

"(4) Special effective date.—The amendment made by subsection (c)(1) [amending this section] shall take effect on the date of enactment of this Act [June 22, 2009]."

**Effective Date of 2007 Amendment**

Amendment by sections 901(d)(4) and 902(b) of Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of this title.

**Effective Date of 1994 Amendment**

Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146, provided that the amendment made by that section is effective as of the date on which section 1904 of Pub. L. 101–647, which amended this section, took effect.

**Effective Date of 1990 Amendment**

Pub. L. 101–629, §17(b), Nov. 28, 1990, 104 Stat. 4528, provided that:

"(b) Effective Date of Application to Device User Facilities.—

"(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act [Nov. 28, 1990]."

"(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act [Nov. 28, 1990] the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333(f)], as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act). [Secretary of Health and Human Services had not made the report required by par. (1) on the expiration of 48 months after Nov. 28, 1990.]"
“(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

“(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report.”

**Effective Date of 1988 Amendment**
Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

**Effective Date of 1976 Amendment**
Amendment by Pub. L. 94–278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94–278, set out as a note under section 334 of this title.

**Effective Date of 1970 Amendment**

**Effective Date of 1968 Amendment**
Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

**Effective Date of 1965 Amendment**

**Effective Date of 1960 Amendment**

**Effective Date of 1951 Amendment**

**Savings Provision**
Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.
TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

GUIDANCE


"(1) In general.—The Secretary of Health and Human Services shall issue guidance [see 76 F.R. 22905, effective Apr. 15, 2011]—

"(A) defining the term 'repeated violation', as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

"(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provider [sic] such agent information to the Food and Drug Administration prior to the violation;

"(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

"(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

"(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

"(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

"(i) adopting and enforcing a written policy against sales to minors;
"(ii) informing its employees of all applicable laws;
"(iii) establishing disciplinary sanctions for employee noncompliance; and
"(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

"(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum
age requirements for the sale of tobacco products, including the steps listed in subparagraph (F).

"(2) Penalties for violations.—

"(A) In general.—The amount of the civil penalty to be applied for violations of restrictions promulgated under section 906(d) [probably means section 906(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 387f(d)], as described in paragraph (1), shall be as follows:

"(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

"(I) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;
"(II) in the case of a second violation within a 12-month period, $250;
"(III) in the case of a third violation within a 24-month period, $500;
"(IV) in the case of a fourth violation within a 24-month period, $2,000;
"(V) in the case of a fifth violation within a 36-month period, $5,000; and
"(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

"(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

"(I) in the case of the first violation, $250;
"(II) in the case of a second violation within a 12-month period, $500;
"(III) in the case of a third violation within a 24-month period, $1,000;
"(IV) in the case of a fourth violation within a 24-month period, $2,000;
"(V) in the case of a fifth violation within a 36-month period, $5,000; and
"(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

"(B) Training program.—For purposes of subparagraph (A), the term 'approved training program' means a training program that complies with standards developed by the Food and Drug Administration for such programs.

"(C) Consideration of state penalties.—The Secretary shall coordinate with the States in enforcing the provisions of this Act [probably means div. A of Pub. L. 111–31, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables for classifications] and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under section 906(d) [21 U.S.C. 387f(d)], shall consider the amount of any penalties paid by the retailer to a State for the same violation."

**Construction of 2011 Amendment**

Nothing in amendment by Pub. L. 111–353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

**Enforcement**

Pub. L. 99–660, title I, §103, Nov. 14, 1986, 100 Stat. 3751, provided that: "For the fines authorized to be imposed under section 303 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333], see section 3623 of title 18, United States Code, for the period ending October 31, 1986 [probably should be October 31, 1987], and sections 3559 and 3571 of such title for the period beginning November 1, 1986 [probably should be November 1, 1987]."
§351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated-

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is
labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) Mixture with or substitution of another substance

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e) Devices not in conformity with performance standards

(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 360d of this title unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 360d(c) of this title unless such device is in all respects in conformity with such standard.

(f) Certain class III devices

(1) If it is a class III device-

(A)(i) which is required by an order issued under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the issuance of such order, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 360c(f) of this title into class III, which under section 360e(a) of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(l) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 360c(f) of this title into class III and intended solely for investigational use, paragraph 1 (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to an order issued under subsection (b) of section 360e of this title, paragraph 1 (1) shall not apply with respect to such device during the period ending-

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360c of this title, or

(ii) on the ninetieth day after the date of the issuance of such order,
whichever occurs later.

(3) In the case of a device with respect to which a regulation was promulgated under section 360e(b) of this title prior to July 9, 2012, a reference in this subsection to an order issued under section 360e(b) of this title shall be deemed to include such regulation.

(g) Banned devices
If it is a banned device.

(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions
If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 360j(f)(1) of this title or an applicable condition prescribed by an order under section 360j(f)(2) of this title.

(i) Failure to comply with requirements under which device was exempted for investigational use
If it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(j) Delayed, denied, or limited inspection; refusal to permit entry or inspection
If it is a drug or device and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

For purposes of paragraph (a)(2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.


AMENDMENTS
2017—Par. (j). Pub. L. 115–52 inserted "or device" after "drug".


1997-Par. (a)(2)(C). Pub. L. 105–115, §121(b)(1), inserted "; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess;" before "or (3)".

Par. (e). Pub. L. 105–115, §204(c), designated existing provisions as subpar. (1) and added subpar. (2).

1992-Par. (a)(4). Pub. L. 102–571 substituted "379e(a)" for "376(a)" in cls. (A) and (B).

1990-Par. (f)(1). Pub. L. 101–629, §9(b), which directed the amendment of subpars. (A) to (C) of par. (f), was executed by making the amendments in cls. (A) to (C) of subpar. (1) of par. (f) as follows to reflect the probable intent of Congress: in cl. (A)(ii)(II), substituted ", suspended, or withdrawn" for "or withdrawn"; in cl. (B)(ii), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect"; and in cl. (C), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect".

1976-Par. (a). Pub. L. 94–295, §9(b)(1), substituted "(3) if its" for "(3) if it is a drug and its" in cl. (3), substituted "(4) if (A) it bears or contains" for "(4) if (A) it is a drug which bears or contains" in cl. (4)(A), and substituted "drugs or devices" for "drugs" in cl. (4)(B).

 Pars. (e) to (i). Pub. L. 94–295, §3(d), added pars. (e) to (i).

1968-Par. (a). Pub. L. 90–399 added cls. (5) and (6).

1962-Par. (a). Pub. L. 87–781 designated existing provisions of cl. (2) as (A) and added (B).

1960-Par. (a). Pub. L. 86–618 substituted provisions in cl. (4) relating to unsafe color additives for provisions which related to a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

Effective and Termination Dates of 1997 Amendment

Pub. L. 105–115, title I, §121(b)(2), Nov. 21, 1997, 111 Stat. 2320, provided that: "Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act [Nov. 21, 1997] or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B) [section 121(c)(1)(B) of Pub. L. 105–115, set out as a note under section 355 of this title], whichever is later."

**EFFECTIVE DATE OF 1968 AMENDMENT**
Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

**EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS**
Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

**EFFECTIVE DATE OF 1960 AMENDMENT**

**EFFECTIVE DATE; POSTPONEMENT**
Par. (a)(4) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

**TRANSFER OF FUNCTIONS**
For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**APPROVAL BY REGULATION PRIOR TO JULY 9, 2012**
Pub. L. 112–144, title VI, §608(b)(3), July 9, 2012, 126 Stat. 1059, provided that: "The amendments made by this subsection [amending this section and section 360e of this title] shall have no effect on a regulation that was promulgated prior to the date of enactment of this Act [July 9, 2012] requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval."

**GUIDANCE**
Pub. L. 112–144, title VII, §707(b), July 9, 2012, 126 Stat. 1068, provided that: "Not later than 1 year after the date of enactment of this section [July 9, 2012], the Secretary of Health and Human Services shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351(j)] (as added by subsection (a))."

1 So in original. Probably should be "subparagraph".

§352. Misbranded drugs and devices
A drug or device shall be deemed to be misbranded-

(a) False or misleading label
(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under
this paragraph if the health care economic information relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 355 of this title or under section 262 of title 42. The requirements set forth in section 355(a) of this title or in subsections (a) and (k) of section 262 of title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

(2)(A) For purposes of this paragraph, the term "health care economic information" means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved under section 355 of this title or under section 262 of title 42 for such drug.

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.


(e) Designation of drugs or devices by established names

(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)-

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary,
on the immediate container, as prescribed in regulation promulgated by the Secretary, except
that nothing in this subclause shall be deemed to require that any trade secret be divulged,
and except that the requirements of this subclause with respect to alphabetical order shall
apply only to nonprescription drugs that are not also cosmetics and that this subclause shall
not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case
may be, on such label (and on any labeling on which a name for such drug or ingredient is
used) shall be printed prominently and in type at least half as large as that used thereon for any
proprietary name or designation for such drug or ingredient, except that to the extent that
compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is
impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of
any other nonproprietary name, its established name (as defined in subparagraph (4))
prominently printed in type at least half as large as that used thereon for any proprietary name
or designation for such device, except that to the extent compliance with the requirements of
this subparagraph is impracticable, exemptions shall be established by regulations promulgated
by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or
ingredient thereof, means (A) the applicable official name designated pursuant to section 358 of
this title, or (B), if there is no such name and such drug, or such ingredient, is an article
recognized in an official compendium, then the official title thereof in such compendium, or (C) if
neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name,
if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph
applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic
Pharmacopoeia under different official titles, the official title used in the United States
Pharmacopoeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in
which case the official title used in the Homoeopathic Pharmacopoeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means
(A) the applicable official name of the device designated pursuant to section 358 of this title, (B)
if there is no such name and such device is an article recognized in an official compendium,
then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of
this subparagraph applies, then any common or usual name of such device.

(f) Directions for use and warnings on label

 Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings
against use in those pathological conditions or by children where its use may be dangerous to
health, or against unsafe dosage or methods or duration of administration or application, in such
manner and form, as are necessary for the protection of users, except that where any
requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary
for the protection of the public health, the Secretary shall promulgate regulations exempting
such drug or device from such requirement. Required labeling for prescription devices intended
for use in health care facilities or by a health care professional and required labeling for in vitro
diagnostic devices intended for use by health care professionals or in blood establishments may
be made available solely by electronic means, provided that the labeling complies with all
applicable requirements of law, and that the manufacturer affords such users the opportunity to
request the labeling in paper form, and after such request, promptly provides the requested
information without additional cost.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements
for designation of drug
If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) Deteriorative drugs; packing and labeling

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.


(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088. ", except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug,
published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 353(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) Drugs or devices from nonregistered establishments

If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 360 of this title, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 381(s) of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360(e) of this title.

(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15. This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

(s) Devices subject to performance standards not bearing requisite labeling
If it is a device subject to a performance standard established under section 360d of this title, unless it bears such labeling as may be prescribed in such performance standard.

(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 360h of this title respecting the device, (2) to furnish any material or information required by or under section 360i of this title respecting the device, or (3) to comply with a requirement under section 360l of this title.

(u) Identification of manufacturer

(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) Reprocessed single-use devices

If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) New animal drugs

If it is a new animal drug-

(1) that is conditionally approved under section 360ccc of this title and its labeling does not conform with the approved application or section 360ccc(f) of this title, or that is not conditionally approved under section 360ccc of this title and its label bears the statement set forth in section 360ccc(f)(1)(A) of this title; or

(2) that is indexed under section 360ccc–1 of this title and its labeling does not conform with the index listing under section 360ccc–1(e) of this title or 360ccc–1(h) of this title, or that has not been indexed under section 360ccc–1 of this title and its label bears the statement set forth in section 360ccc–1(h) of this title.

(x) Nonprescription drugs

If it is a nonprescription drug (as defined in section 379aa of this title) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 379aa of this title) may receive a report of a serious adverse event (as defined in section 379aa of this title) with such drug.

(y) Drugs subject to approved risk evaluation and mitigation strategy

If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 355(p) of this title and the responsible person (as such term is used in section 355–1 of this title) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 355–1 of this title.

(z) Postmarket studies and clinical trials; new safety information in labeling
If it is a drug, and the responsible person (as such term is used in section 355(o) of this title) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 355(o) of this title with respect to such drug.

(aa) Unpaid fees; failure to submit identifying information

If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 379j–42(a)(4) of this title or for which identifying information required by section 379j–42(f) of this title has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) False or misleading advertisement or promotion of compounded drug

If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) Failure to bear product identifier

If it is a drug and it fails to bear the product identifier as required by section 360eee–1 of this title.

(dd) Improper labeling of antimicrobial drugs

If it is an antimicrobial drug, as defined in section 360a–2(f) of this title, and its labeling fails to conform with the requirements under section 360a–2(d) of this title.


AMENDMENTS

2016-Subsec. (a). Pub. L. 114–255, §3037, designated existing provisions as par. (1), substituted "a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement" for "a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations", "relates" for "directly relates", and ",", is based on
competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 355 of this title or under section 262 of title 42. The requirements set forth in section 355(a) of this title or in subsections (a) and (k) of section 262 of title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph for "and is based on competent and reliable scientific evidence. The requirements set forth in section 355(a) of this title or in section 262(a) of title 42 shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph", struck out "In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention." at end, and added par. (2).


2012-Par. (o). Pub. L. 112–144, §714(c), inserted "if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 381(s) of this title," after "not duly registered under section 360 of this title.".

Pub. L. 112–144, §702(a), struck out "in any State" after "establishment".


2007-Par. (n). Pub. L. 110–85, §906(a), inserted "and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.'," after "section 371(a) of this title,".

Pub. L. 110–85, §901(d)(6), substituted "section 371(a) of this title" for "the procedure specified in section 371(e) of this title".

Pub. L. 110–85, §901(d)(3)(A), inserted at end "In the case of an advertisement for a drug subject to section 353(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner."

Pars. (y), (z). Pub. L. 110–85, §902(a), added pars. (y) and (z).


2005-Par. (u). Pub. L. 109–43 amended par. (u) generally. Prior to amendment, par. (u) read as follows: "If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device."
2004—Par. (f). Pub. L. 108–214, in last sentence, inserted "or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments" after "in health care facilities", inserted comma after "means", substituted "requirements of law, and that the manufacturer affords such users the opportunity" for "requirements of law and, that the manufacturer affords health care facilities the opportunity", and struck out "the health care facility" after "promptly provides".


2002—Par. (f). Pub. L. 107–250, §206, inserted at end "Required labeling for prescription devices intended for use in health care facilities may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law and, that the manufacturer affords health care facilities the opportunity to request the labeling in paper form, and after such request, promptly provides the health care facility the requested information without additional cost."

Par. (u). Pub. L. 107–250, §301(a), which directed amendment of section by adding par. (u) at end, was executed by adding par. (u) before par. (v) to reflect the probable intent of Congress.


1997—Par. (a). Pub. L. 105–115, §114(a), inserted at end "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 355(a) of this title or in section 262(a) of title 42 shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."

Par. (d). Pub. L. 105–115, §126(b), struck out par. (d) which read as follows: "If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning-May be habit forming.' "

Par. (e)(1). Pub. L. 105–115, §412(c), amended subpar. (1) generally. Prior to amendment, subpar. (1) read as follows: "If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any
bromides, ether, chloroform, acetanilid, acethphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscynamine, arsenic, digitalis, digitalis glucosides, mercury ouabain strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

Par. (k). Pub. L. 105–115, §125(a)(2)(B), struck out par. (k) which read as follows: "If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 356 of this title, and (2) such certificate or release is in effect with respect to such drug."

Par. (l). Pub. L. 105–115, §125(b)(2)(D), struck out par. (l) which read as follows: "If it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlorotetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title."

1993-Par. (e)(3). Pub. L. 103–80, §3(m)(1), substituted "of such ingredient, except that" for "of such ingredient: *Provided*, That."

Par. (f). Pub. L. 103–80, §3(m)(2), substituted "users, except that where" for "users: *Provided*, That where".

Par. (g). Pub. L. 103–80, §3(m)(3), substituted "prescribed therein. The method" for "prescribed therein: *Provided*, That the method" and "Pharmacopoeia, except that" for "Pharmacopoeia: *Provided further, That.*"

Par. (n). Pub. L. 103–80, §3(m)(4), substituted ", except that (A)" for ": *Provided*, That (A)."


1976-Par. (e). Pub. L. 94–295, §5(a), substituted "subparagraph (3)" for "subparagraph (2)" in subpar. (1), added subpar. (2), redesignated former subpar. (2) as (3) and in subpar. (3) as so redesignated substituted "subparagraph (1)" for "this paragraph (e)", and added subpar. (4).

Par. (j). Pub. L. 94–295, §3(e)(2), substituted "dosage or manner," for "dosage, ."

Par. (m). Pub. L. 94–295, §9(b)(2), substituted "the intended use of which is for" for "the intended use of which in or on drugs is for"
Par. (o). Pub. L. 94–295, §4(b)(2), substituted "If it was manufactured" for "If it is a drug and was manufactured" and inserted ", if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires".

Pars. (q) to (t). Pub. L. 94–295, §3(e)(1), added pars. (q) to (t).


1968—Par. (l). Pub. L. 90–399 inserted "(except a drug for use in animals other than man)" after "represented as a drug".

1962—Par. (e). Pub. L. 87–781, §112(a), designated existing provisions as subpar. (1), substituted ", unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2) of this subsection) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity" for "and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name", and "the established name" for "the name", provided that the requirement for stating the quantity of active ingredients, other than those specified in this par., applies only to prescription drugs, and that the established name of a drug on a label is to be printed prominently and in type at least half as large as used for any proprietary designation, and added subpar. (2) defining "established name".

Par. (g). Pub. L. 87–781, §112(b), provided that if there is an inconsistency between the provisions of this par. and those of par. (e), as to the name of a drug, the requirements of par. (e) should prevail.

Par. (l). Pub. L. 87–781, §105(c), substituted "bacitracin, or any other antibiotic drug" for "or bacitracin."


1953—Par. (l). Act Aug. 5, 1953, substituted "chlortetracycline" for "aureomycin".

1949—Par. (l). Act July 13, 1949, inserted ", aureomycin, chloramphenicol, or bacitracin" after "streptomycin".

1947—Par. (l). Act Mar. 10, 1947, inserted "or streptomycin" after "penicillin".


1941—Par. (k). Act Dec. 22, 1941, added par. (k).

1939—Par. (d). Act June 29, 1939, substituted "name, and quality or proportion" for "name, quantity, and percentage".
**Effective Date of 2012 Amendment**

**Effective Date of 2007 Amendment**

**Effective Date of 2006 Amendment**

"(1) In general.—Except as provided in paragraph (2), the amendments made by this section [enacting section 379aa of this title and amending this section and section 331 of this title] shall take effect 1 year after the date of enactment of this Act [Dec. 22, 2006].

"(2) Misbranding.—Section 502(x) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(x)] (as added by this section) shall apply to any nonprescription drug (as defined in such section 502(x)) labeled on or after the date that is 1 year after the date of enactment of this Act [Dec. 22, 2006]."

**Effective Date of 2002 Amendment**

"(1) shall be effective—

"(A) with respect to devices described under paragraph (1) of such section, 12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005 [Aug. 1, 2005], or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, whichever is later; and

"(B) with respect to devices described under paragraph (2) of such section 502(u), 12 months after such date of enactment; and

"(2) shall apply only to devices reprocessed and introduced or delivered for introduction in interstate commerce after such applicable effective date."

Pub. L. 107–250, title III, §302(a)(2), Oct. 26, 2002, 116 Stat. 1616, provided that: "The amendment made by paragraph (1) [amending this section] takes effect 15 months after the date of the enactment of this Act [Oct. 26, 2002], and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date."

**Effective Date of 1997 Amendment**
Amendment by sections 114(a), 126(b), and 412(c) of Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.
**Effective Date of 1978 Amendment**

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

**Effective Date of 1970 Amendment**

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

**Effective Date of 1968 Amendment**

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

**Effective Date of 1962 Amendment**

Pub. L. 87–781, title I, §112(c), Oct. 10, 1962, 76 Stat. 791, provided that: "This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962]."

Pub. L. 87–781, title I, §131(b), Oct. 10, 1962, 76 Stat. 792, provided that: "No drug which was being commercially distributed prior to the date of enactment of this Act [Oct. 10, 1962] shall be deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(n)], as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(e)]."

Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

**Effective Date of 1960 Amendment**


**Effective Date; Postponement**

Pars. (b) and (d) to (h) effective Jan. 1, 1940, and such paragraphs effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date: Postponement in Certain Cases note under section 301 of this title.

**Regulations**

Pub. L. 110–85, title IX, §901(d)(3)(B), Sept. 27, 2007, 121 Stat. 940, provided that: "Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 [Sept. 27, 2007], the Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in section 502(n) of the Federal Food, Drug,
and Cosmetic Act (21 U.S.C. 352(n)) (as amended by subparagraph (A)) is presented in the manner required under such section.

**Construction of 2016 Amendment**

Nothing in amendment by section 3044(b)(2) of Pub. L. 114–255 to be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under section 356(h) of this title, by health care professionals, or to limit the practice of health care, see section 3043 of Pub. L. 114–255, set out as a note under section 356 of this title.

**Transfer of Functions**

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**Presentation of Prescription Drug Benefit and Risk Information**


"(a) In General.-The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

"(b) Review and Consultation.-In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.

"(c) Report.-Not later than 1 year after the date of enactment of this Act [Mar. 23, 2010], the Secretary shall submit to Congress a report that provides-

"(1) the determination by the Secretary under subsection (a); and

"(2) the reasoning and analysis underlying that determination.

"(d) Authority.-If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

"(e) Clarification.-Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information."

**Guidance; Misbranded Devices**

Pub. L. 109–43, §2(c)(2), Aug. 1, 2005, 119 Stat. 441, provided that: "Not later than 180 days after the date of enactment of this Act [Aug. 1, 2005], the Secretary of Health and Human Services shall issue guidance to identify circumstances in which the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, is not 'prominent and conspicuous',
as used in section 502(u) of Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(u)] (as amended by paragraph (1))."

**STUDIES**

Pub. L. 110–85, title IX, §906(b), Sept. 27, 2007, 121 Stat. 950, provided that:

"(1) In general.—In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, in consultation with the Advisory Committee on Risk Communication under section 567 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–6] (as added by section 917), shall, not later than 6 months after the date of the enactment of this Act [Sept. 27, 2007], conduct a study to determine if the statement in section 502(n) of such Act [21 U.S.C. 352(n)] (as added by subsection (a)) required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements.

"(2) Content.—As part of the study under paragraph (1), such Secretary shall consider whether the information in the statement described in paragraph (1) would detract from the presentation of risk information in a direct-to-consumer television advertisement. If such Secretary determines the inclusion of such statement is appropriate in direct-to-consumer television advertisements, such Secretary shall issue regulations requiring the implementation of such statement in direct-to-consumer television advertisements, including determining a reasonable length of time for displaying the statement in such advertisements. The Secretary shall report to the appropriate committees of Congress the findings of such study and any plans to issue regulations under this paragraph."


Pub. L. 105–115, title I, §114(b), Nov. 21, 1997, 111 Stat. 2312, provided that: "The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a) [amending this section]. Not later than 4 years and 6 months after the date of enactment of this Act [Nov. 21, 1997], the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study."

**COUNTERFEITING OF DRUGS; CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY**

Pub. L. 89–74, §9(a), July 15, 1965, 79 Stat. 234, provided that: "The Congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine; that, while such drugs are deemed misbranded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(i)], the controls for the suppression of the traffic in such drugs are inadequate because of the difficulty of determining the place of interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls with respect to such drugs without regard to their interstate or intrastate origins."
§353. Exemptions and consideration for certain drugs, devices, and biological products

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which-

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).
(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of title 26, or to marihuana as defined in section 4761 of title 26.

c) Sales restrictions

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug-
   (i) which is subject to subsection (b), and
   (ii)(I) which was purchased by a public or private hospital or other health care entity, or
   (II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of title 26.

(B) Subparagraph (A) does not apply to-
   (i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,
   (ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,
   (iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,
   (iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or
   (v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

d) Distribution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a-
   (A) practitioner licensed to prescribe such drug,
(B) health care professional acting at the direction and under the supervision of such a practitioner, or
(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made-
   (i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and
   (ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain-
   (i) the name, address, professional designation, and signature of the practitioner making the request,
   (ii) the identity of the drug sample requested and the quantity requested,
   (iii) the name of the manufacturer of the drug sample requested, and
   (iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed-
   (i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or
   (ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of
(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(4) In this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(e) Licensing and reporting requirements for wholesale distributors; fees; definitions

(1) Requirement.-Subject to section 360eee–2 of this title:

(A) In general.-No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person-

(i)(I) is licensed by the State from which the drug is distributed; or

(ii) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) Standards.-Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 360eee–2 of this title.

(2) Reporting and database.-
(A) Reporting.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) Database.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) Coordination.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) Confidentiality.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(3) Costs.—

(A) Authorized fees of secretary.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(B) State licensing fees.—Nothing in this chapter shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.
(4) For the purposes of this subsection and subsection (d), the term "wholesale distribution" means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include-

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act [42 U.S.C. 247d], except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 360eee–1(e) of this title;

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if-

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360(b)(2) of this title;

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit-

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is-

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;
(II) a product intended to maintain the equilibrium of water and minerals in the body;
(III) a product intended for irrigation or reconstitution;
(IV) an anesthetic;
(V) an anticoagulant;
(VI) a vasopressor; or
(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
(Q) the distribution of medical gas, as defined in section 360ddd of this title;
(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 360eee(16)(B) of this title and registered under section 360 of this title for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(5) Third-party logistics providers.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 360eee(22) of this title shall obtain a license as a third-party logistics provider as described in section 360eee–3(a) of this title and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(6) Affiliate.—For purposes of this subsection, the term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—
(A) one business entity controls, or has the power to control, the other business entity; or
(B) a third party controls, or has the power to control, both of the business entities.

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—
(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or
(ii) is limited by an approved application under subsection (b) of section 360b of this title, a conditionally-approved application under section 360ccc of this title, or an index listing under section 360ccc–1 of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.
(B) For purposes of subparagraph (A), an order is lawful if the order-
   (i) is a prescription or other order authorized by law,
   (ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order,
   and filed by that person, and
   (iii) is refilled only if authorized in the original order or in a subsequent oral order promptly
   reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed
   to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection-
   (A) shall be exempt from the requirements of section 352 of this title, except subsections
   (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and
   (B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of
   such section, if-
      (i) when dispensed by a licensed veterinarian, the drug bears a label containing the
          name and address of the practitioner and any directions for use and cautionary statements
          specified by the practitioner, or
      (ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a
          label containing the name and address of the dispenser, the serial number and date of the
          order or of its filling, the name of the licensed veterinarian, and the directions for use and
          cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of
a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject
to section 360b, 360ccc, or 360ccc–1 of this title from the requirements of paragraph (1) when
such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time
prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to
use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply
shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement
specified in the preceding sentence.

(g) Regulation of combination products

(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency
center to regulate products that constitute a combination of a drug, device, or biological product.

(B) The Secretary shall conduct the premarket review of any combination product under a
single application, whenever appropriate.

(C) For purposes of this subsection, the term "primary mode of action" means the single
mode of action of a combination product expected to make the greatest contribution to the
overall intended therapeutic effects of the combination product.

(D) The Secretary shall determine the primary mode of action of the combination product. If
the Secretary determines that the primary mode of action is that of-
   (i) a drug (other than a biological product), the agency center charged with premarket
review of drugs shall have primary jurisdiction;
   (ii) a device, the agency center charged with premarket review of devices shall have
primary jurisdiction; or
   (iii) a biological product, the agency center charged with premarket review of biological
products shall have primary jurisdiction.
(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)-

(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

(2)(A) (i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving such request, meet with the sponsor of such combination product.

(ii) A meeting under clause (i) may-

(I) address the standards and requirements for market approval or clearance of the combination product;

(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

(iv) Any such agreement shall remain in effect, except-

(I) upon the written agreement of the Secretary and the sponsor or applicant; or

(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] applicable to the combination product has been identified since
(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this chapter or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

(4) For purposes of paragraph (3), an approved constituent part is—

(A) a drug constituent part of a combination product being reviewed in a single application or request under section 360e, 360(k), or 360c(f)(2) of this title (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

(B) a device constituent part approved under section 360e of this title that is referenced by the sponsor and that is available for use by the Secretary under section 360j(h)(4) of this title; or

(C) any constituent part that was previously approved, cleared, or classified under section 355, 360(k), 360c(f)(2), or 360e of this title for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 379aa(a)(2) of this title.

(5)(A) If an application is submitted under section 360e or 360(k) of this title or a request is submitted under section 360c(f)(2) of this title, consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

(i) the application or request shall include the certification or statement described in section 355(b)(2) of this title; and

(ii) the applicant or requester shall provide notice as described in section 355(b)(3) of this title.

(B) For purposes of this paragraph and paragraph (4), the term "approved drug" means an active ingredient—

(i) that was in an application previously approved under section 355(c) of this title;

(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request...
were an application described in section 355(b)(2) of this title that referenced the approved drug:

(i) Subparagraphs (A), (B), (C), and (D) of section 355(c)(3) of this title.
(ii) Clauses (ii), (iii), and (iv) of section 355(c)(3)(E) of this title.
(iii) Subsections (b) and (c) of section 355a of this title.
(iv) Section 355f(a) of this title.
(v) Section 360cc(a) of this title.

(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 355(b)(2) of this title for purposes of section 271(e)(2)(A) of title 35.

(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.

(7) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(8)(A) Not later than 60 days after October 26, 2002, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the "Office") shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.

(ii) In order to ensure the timeliness and alignment of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness and alignment of the premarket review.

(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

(iv) The Office shall, with respect to the premarket review of a combination product-

(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;
(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and
(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

(v) In seeking agency action with respect to a combination product, the sponsor of such product-
(I) shall identify the product as a combination product; and
(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

(vi) Not later than 4 years after December 13, 2016, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes-
(I) the structured process for managing pre-submission interactions with sponsors developing combination products;
(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;
(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2).

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.
(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after October 26, 2002 (except with respect to clause (iv), beginning not later than one year after December 13, 2016), and annually thereafter, the
Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions-

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;
(ii) identifying the number of premarket reviews of such products that involved a consulting agency center;
(iii) describing improvements in the consistency of postmarket regulation of combination products; and
(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product’s sponsor.

(H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

(9) As used in this subsection:
(A) The term "agency center" means a center or alternative organizational component of the Food and Drug Administration.
(B) The term "biological product" has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).
(C) The term "market clearance" includes-
(i) approval of an application under section 355, 357, 360e, or 360j(g) of this title;
(ii) a finding of substantial equivalence under this part;
(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262); and
(iv) de novo classification under section 360c(a)(1) of this title.

(D) The terms "premarket review" and "reviews" include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 355, 360(k), 360c(f)(2), 360e, or 360j of this title or under section 351 of the Public Health Service Act [42 U.S.C. 262], including with respect to investigational use of the product.

References in Text

The Public Health Service Act, referred to in subsec. (g)(2)(A)(iv)(II), (3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.


CODIFICATION

In subsec. (b)(5), "sections 4721, 6001, and 6151 of title 26" and "section 4761 of title 26" substituted for "section 3220 of the Internal Revenue Code (26 U.S.C. 3220)" and "section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b))", respectively, on authority of section 7852(b) of Title 26, Internal Revenue Code.

AMENDMENTS

2016—Subsec. (g)(1). Pub. L. 114–255, §3038(a)(4), added par. (1) and struck out former par. (1) which read as follows: "The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

"(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

"(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction."


Subsec. (g)(3). Pub. L. 114–255, §3038(a)(1), (4), added par. (3) and struck out former par. (3) which read as follows: "The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990."

Subsec. (g)(4) to (6). Pub. L. 114–255, §3038(a)(4), added pars. (4) to (6). Former pars. (4) and (5) redesignated (8) and (9), respectively.


Subsec. (g)(8)(C)(i). Pub. L. 114–255, §3038(a)(5)(A)(i), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: "In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center."


Subsec. (g)(9)(C). Pub. L. 114–255, §3038(a)(6)(A), substituted semicolon for comma at end of cl. (i), semicolon for ", and" at end of cl. (ii), and "; and" for period at end of cl. (iii), and added cl. (iv).


Subsec. (e). Pub. L. 113–54, §204(a)(1)–(4), added pars. (1) to (6) and struck out former pars. (1) to (3). Prior to amendment, pars. (1) to (3) set out certain disclosure and licensing requirements for wholesale distributors and defined "authorized distributors of record" and "wholesale distribution".


Subsec. (f)(3). Pub. L. 108–282, §102(b)(5)(F)(ii), substituted "section 360b, 360ccc, or 360ccc–1" for "section 360b".

2002—Subsec. (g)(1). Pub. L. 107–250, §204(1)(A), substituted "shall in accordance with this subsection assign an agency center" for "shall designate a component of the Food and Drug Administration" in first sentence of introductory provisions.

Subsec. (g)(1)(A) to (C). Pub. L. 107–250, §204(1)(B), substituted "the agency center charged" for "the persons charged".


Subsec. (g)(5). Pub. L. 107–250, §204(2), (4), redesignated par. (4) as (5), added subpar. (A), and redesignated former subpars. (A) and (B) as (B) and (C), respectively.

1997—Subsec. (b)(1)(A) to (C). Pub. L. 105–115, §126(c)(1), redesignated subpars. (B) and (C) as (A) and (B), respectively, and struck out former subpar. (A), which read as follows: "is a habit-forming drug to which section 352(d) of this title applies; or".

Subsec. (b)(3). Pub. L. 105–115, §126(c)(2), struck out reference to section 352(d) of this title before "355".

Subsec. (b)(4). Pub. L. 105–115, §126(a), amended par. (4) generally. Prior to amendment, par. (4) read as follows: "A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription'. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence."

Subsec. (g)(4)(A). Pub. L. 105–115, §123(e)(1), substituted "section 351(i)" for "section 351(a)" and "262(i)" for "262(a)".
Subsec. (g)(4)(B)(iii). Pub. L. 105–115, §123(e)(2), substituted "biologics license application under subsection (a)" for "product or establishment license under subsection (a) or (d)".


1992-Subsec. (d)(1). Pub. L. 102–353, §4(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample."


Subsec. (e)(1). Pub. L. 102–353, §4(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) of this section and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors."

Subsec. (e)(2)(A). Pub. L. 102–353, §2(a), (d), temporarily inserted "or has registered with the Secretary in accordance with paragraph (3)"). See Termination Date of 1992 Amendment note below.


Subsec. (e)(4). Pub. L. 102–353, §4(4), inserted "and subsection (d) of this section" after "For the purposes of this subsection".

Pub. L. 102–353, §2(b), (d), temporarily redesignated par. (3) as (4). See Termination Date of 1992 Amendment note below.

Subsec. (f)(1)(B). Pub. L. 102–353, §2(c), which directed the substitution of "an order" for "and order", could not be executed because "and order" did not appear in subpar. (B).

Subsec. (g)(3). Pub. L. 102–300 substituted "clearance" for "approval".


Subsec. (c)(2), (3)(B)(v). Pub. L. 102–108, §2(d)(1), made technical amendment to reference to subsection (b) of this section involving corresponding provision of original act.


Pub. L. 102–108, §2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f).


1988-Subsec. (c). Pub. L. 100–670 added subsec. (c) relating to veterinary prescription drugs.

Pub. L. 100–293, §4, added subsec. (c) relating to sales restrictions.


Subsec. (e). Pub. L. 100–293, §6, added subsec. (e).


1951-Subsec. (b). Act Oct. 26, 1951, amended subsec. (b) generally to protect the public from abuses in the sale of potent prescription drugs, and to relieve retail pharmacists and the public from unnecessary restrictions on the dispensation of drugs that are safe to use without supervision of a doctor.

**Effective Date of 2013 Amendment**
Pub. L. 113–54, title II, §204(c), Nov. 27, 2013, 127 Stat. 636, provided that: "The amendments made by subsections (a) and (b) [enacting section 360eee–2 of this title and amending this section] shall take effect on January 1, 2015."

**Effective Date of 1997 Amendment**

**Termination Date of 1992 Amendment**
Pub. L. 102–353, §2(d), Aug. 26, 1992, 106 Stat. 941, provided that: "Effective September 14, 1994, the amendments made by subsections (a) and (b) [amending this section] shall no longer be in effect."

**Effective Date of 1988 Amendment**
Pub. L. 100–293, §8, Apr. 22, 1988, 102 Stat. 100, provided that:

"(a) General Rule.-Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section and sections 331, 333, and 381 of this title and enacting provisions set out as notes under this section and section 301 of this title] shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Apr. 22, 1988]."

"(b) Exception.-"

"(1) Section 503(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(d)] (as added by section 5 of this Act) shall take effect upon the expiration of 180 days after the date of the enactment of this Act [Apr. 22, 1988]."

245
"(2) The Secretary of Health and Human Services shall by regulation issue the guidelines required by section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(e)(2)(B)] (as added by section 6 of this Act) not later than 180 days after the date of the enactment of this Act. Section 503(e)(2)(A) of such Act shall take effect upon the expiration of 2 years after the date such regulations are promulgated and take effect."

**Effective Date of 1970 Amendment**
Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

**Effective Date of 1962 Amendment**

**Effective Date of 1951 Amendment**

**Transfer of Functions**
For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**Effective Medication Guides**
Pub. L. 104–180, title VI, §601, Aug. 6, 1996, 110 Stat. 1593, provided that:

"(a) In General.-Not later than 30 days after the date of enactment of this Act [Aug. 6, 1996], the Secretary of the Department of Health and Human Services shall request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule of the Food and Drug Administration on 'Prescription Drug Product Labeling: Medication Guide Requirements' (60 Fed. Reg. 44182; relating to the provision of oral and written prescription information to consumers).

"(b) Goals.-Goals consistent with the proposed rule described in subsection (a) are the distribution of useful written information to 75 percent of individuals receiving new prescriptions [sic] by the year 2000 and to 95 percent by the year 2006.

"(c) Plan.-The plan described in subsection (a) shall-

"(1) identify the plan goals;

"(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers;

"(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment;
“(4) contain elements necessary to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.

“(5) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers; and

“(6) provide for compliance with relevant State board regulations.

“(d) Limitation on the Authority of the Secretary.-The Secretary of the Department of Health and Human Services shall have no authority to implement the proposed rule described in subsection (a), or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if, (1) not later than 120 days after the date of enactment of this Act [Aug. 6, 1996], the national organizations described in subsection (a) develop and submit to the Secretary for Health and Human Services a comprehensive, long-range action plan (as described in subsection (a)) which shall be acceptable to the Secretary of Health and Human Services; (2) the aforementioned plan is submitted to the Secretary for review and acceptance: Provided, That the Secretary shall give due consideration to the submitted plan and that any such acceptance shall not be arbitrarily withheld; and (3) the implementation of (a) a plan accepted by the Secretary commences within 30 days of the Secretary's acceptance of such plan, or (b) the plan submitted to the Secretary commences within 60 days of the submission of such plan if the Secretary fails to take any action on the plan within 30 days of the submission of the plan. The Secretary shall accept, reject or suggest modifications to the plan submitted within 30 days of its submission. The Secretary may confer with and assist private parties in the development of the plan described in subsections (a) and (b).

“(e) Secretary Review.-Not later than January 1, 2001, the Secretary of the Department of Health and Human Services shall review the status of private-sector initiatives designed to achieve the goals of the plan described in subsection (a), and if such goals are not achieved, the limitation in subsection (d) shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals.”

**CONGRESSIONAL FINDINGS**

Pub. L. 100–293, §2, Apr. 22, 1988, 102 Stat. 95, provided that: "The Congress finds the following:

“(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

“(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

“(3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

“(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

247
“(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

“(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

“(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

“(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.”

1 So in original. No subpar. (B) has been enacted.

2 So in original. The word "and" probably should appear.

3 So in original. The semicolon probably should be a period.

4 See References in Text note below.