61N-1.001 General Regulations; Definitions.

(1) No change.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.012(6), 499.012(1), 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply to Chapter 499, F.S. and to Rule Chapter 61N-1, F.A.C.:

(a) “Administer” or “administration” – means the obtaining and giving 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 a patient, for his consumption, whether by injection, inhalation, ingestion or any other means.

(b) No change.

(c) “Authorized absence” – means, for purposes of Section 499.012(16)(d),(f), F.S., the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under Section 499.051, F.S., at the time of the inspection, the physical absence of the designated representative from the permitted establishment, pursuant to the written policy developed and maintained by the owner or management of the permitted establishment, for a cumulative period not to exceed 60 calendar days in any 12-month 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 serious health condition, where the employee is needed to care for the a family member (child, spouse or parent) with a serious health condition; or the employee’s own serious health condition makes the employee unable to perform the functions of the designated representative.

(d) “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, Chapter 499, F.S., to purchase, receive or possess those prescription drugs.

The term includes:

1. Any a pharmacy licensed under by Chapter 465, F.S., and authorized under that chapter to possess non-dispensed prescription drugs; 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 a practitioner licensed by Florida law to purchase and receive prescription drugs; or a person who is authorized by the law of the jurisdiction where the delivery occurs to purchase, own, receive, and/or possess those prescription drugs; and

3. A licensed ship captain, or first officer, or designated medical officer for a vessel engaged in international or interstate trade or in trade between ports of the United States and or for any merchant vessel belonging to the U.S. Government, is an authorized recipient for The prescription drugs must be intended solely for emergency medical purposes, and the wholesale distributor must provide deliver the prescription drugs are delivered by the wholesaler directly to the ship/vessel or transfer possession to the appropriate ship’s/vessel’s officer as near to the ship/vessel as state and federal laws allow.

(e) “Broker” – means a person participating in a prescription drug the wholesale distribution by (i) buying, purchasing, or otherwise taking ownership of or title to the drug, (ii) selling or transferring, or offering to sell or transfer, ownership of or title to the drug, (iii) to a person other than the patient or the patient’s agent—without taking physical possession of the drug of a prescription drug that buys and sells the drug but does not take physical possession such that the drug is “sold to” the broker and “shipped to” a third party.

(f) through (m) No change.

(n) “Limited quantities” – pursuant to Section 499.01(3) and(4)(b), F.S., means:

1. Nonclinical/Preclinical – For purposes of nonclinical (not involving the actual use of the product in or on humans or other animals) and preclinical (involving animal use but not human) research and development ("R&D") activities, the number of transactions necessary to advance the program to the clinical stage, provided that the researcher may not acquire or have on hand more than a three-month supply of any product based on forecasts set forth in R&D records created in advance of or contemporaneously with the R&D activities.

2. Clinical – For purposes of clinical trials and biostudies approved by FDA, including filed Investigational New Drug applications (an “IND”) and studies exempt from IND regulations under 21 C.F.R. s. 312.2 (effective 01/01/13), the researcher may engage in the number of transactions necessary to obtain (i) clearance to advance to the next clinical phase of FDA’s approval process (Phase 1 to Phase 2 or Phase 2 to Phase 3), or (ii) for Phase 3 studies, final FDA approval, provided that the researcher may
not acquire or have on hand more than a six-month supply of any product based on forecasts set forth in R&D records created contemporaneously with the R&D activities.

(9H) “Pedigree” – means a document that satisfies the requirements of Section 499.003(31)(a) or (b), F.S., as applicable, and the applicable rule requirements of subsection 61N-1.012(3), F.A.C., and any forms adopted therein.

(9S) “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.

(qp) “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.

(r) “Principal address” – means, as used in Section 499.0121(6), F.S. and any permit application submitted to the department under Chapter 499, F.S., the person’s primary place of business.

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

(tr) “Propagation” of a drug – means, as used under the definition of “manufacture” at Section 499.003(27), F.S., for purposes of permitting under Section 499.013, 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.

(us) “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.

(vs) “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.

(wu) “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 medical convenience 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.

(xx) “Rx” – means prescription.

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

(zx) “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.

(aay) “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.

(bba) “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.

(cca) “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) “Specified drug” means all dosage forms, strengths and container sizes of the following prescription drugs:
1. Bextra (valdecoxib);
2. Celebrex (celecoxib);
3. Combivir (lamivudine/zidovudine);
4. Crixivan (indinavir sulfate);
5. Diflucan (fluconazole);
6. Epivir (lamivudine);
7. Epogen (epoetin alfa);
8. Gamimmune (globulin, immune);
9. Gammagard (globulin, immune);
10. Immune globulin;
11. Lamisil (terbinafine);
12. Lipitor (atorvastatin calcium);
13. Lupron (leuprolide-acetate);
14. Neupogen (filgrastim);
15. Nutropin AQ (somatropin, e-coli derived);
16. Panglobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mammalian derived);
22. Sustiva (efavirenz);
23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
24. Venoglobulin (globulin, immune);
25. Viagra (sildenafil citrate);
26. Videx (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Ziagen (abacavir sulfate);
31. Zocor (simvastatin);
32. Zofran (ondansetron);
33. Zoladex (goserelin acetate); and
34. Zyprexa (olanzapine).

(dd) “State Current Good Manufacturing Practices” means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C.

(ddd) “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.

(eee) “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.

(ggff) “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.

(hhgg) “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.

(hh) “Wholesale distribution” – means distribution of prescription drugs to persons other than a consumer or patient as set forth in Section 499.012(1)(a), F.S.

(ii) “Wholesaler” – means a person who engages in the wholesale distribution of a prescription drug.

(jj) “Written agreement” means any type of written correspondence or documentation to establish an account for ongoing sales of prescription drugs by the manufacturer to that wholesaler.

Rulemaking Authority 499.003(31), 499.024, 499.025(5), 499.01(3), 499.01(4), 499.01(6), 499.0121(6), 499.0122(2), 499.012(12), 499.013(3), 499.014(5), 499.03(4), 499.05 FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 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, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS.

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