AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council

Conference Call Number 888-670-3525
Conference Code 9259887749

May 14, 2015
9:30 a.m.

Council Members:
Gary Cacciatore, Pharm.D., J.D., Chair,
Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Steve Mays, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Jenn Unguru, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Michelle Renae Mendez, DO, Physician
Jeenu Phillips -Board of Pharmacy
Peter Hart, Medical Gas

DBPR Staff:
Reggie Dixon, Division Director
Division of Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Tim Vaccaro, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order: Gary Cacciatore, PharmD., J.D., Chair

TAB 1: Approval of Minutes –February 19, 2015

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD

TAB 3: Division Director's Report – Reginald Dixon
   1. DDC Rules
   2. DDC Workshop Results

TAB 4: Other Business
9:30 a.m. Call to Order by Gary Cacciatore, Chair
The meeting was called to order by the Chair.

The following members were present:
Scott Brock, Dean Ellis, Bill Mahoney, Patrick Barnes, Gary Cacciatore, Mike Ayotte

Dr. Mendez, Jenn Ungru, Peter Hart were present via phone.
Steve Mays was absent due to travel.

TAB 1: Approval of December 11, 2014 Meeting Minutes

Motion by: Mr. Barnes made a motion to approve, Seconded by: Dr. Mendez.
Motion Carried

TAB 2: Chair’s Report – Gary Cacciatore, PharmD, JD

1. Drug Supply Chain Security Act Overview - Martha Russell –Director of Corporate Regulatory Affairs - Cardinal

Ms. Russell gave a presentation to the council for the Drug Supply Chain Security Act.

The presentation material and audio is available on the department website.
Website: http://www.myfloridalicense.com/dbpr/ddc/council_meeting.html

TAB 3: Division Director’s Report – Reginald Dixon

1. DDC Rules Report

Mr. Dixon provided an update to the council on rules.

2. SB 612 Cosmetic Product Registration

Mr. Dixon stated this proposed legislation has been introduced because there has been some concern that we require more than the federal government does with cosmetics. The federal government has a voluntary registration program for cosmetics. This bill removes the mandatory registration of cosmetic products with the department. It relieves the department of obligation for issuing certificates of free sale for those products.

3. 2015 Legislation

Mr. Dixon stated there has been some contact with the House and Senate in regards to changes to Chapter 499. There has been nothing filed to amend Chapter 499.
Mr. Ayotte asked Mr. Dixon when will the Department know if a legislative bill will be filed.

Mr. Dixon stated he does not have a time frame but would let the council know once he has been notified.

Mr. Barnes asked if no bills are filed will there not be any changes to Chapter 499.

Mr. Dixon stated if there are no bills filed Chapter 499 will remain the same. The Department will have to figure out how to regulate or continue regulating the industry and applying the federal standards.

4. *Declaratory Statements / Variance & Waiver - Informational purposes only*

Mr. Ayotte asked if the declaratory statements could be put in topic order on the website.

Mr. Dixon stated the department can look at classifying them on the web page.

Mr. Ellis asked about renewal applications for wholesale distributors will there be any changes.

Mr. Dixon stated because there are no changes to Chapter 499 the renewal process will remain the same.

**TAB 4: Other Business**

Mr. Cacciatore stated he will entertain a motion to adjourn.

Motion by: Mr. Barnes, seconded by Mr. Mahoney. Motion to adjourn
RULES REPORT

To: Drug Wholesale Distributor Advisory Council

From: Reginald D. Dixon, Director

Date: April 27, 2015

Re: Division Rulemaking (rev. 4/27/15)

The following chart is a summary of the Division’s current rulemaking efforts.

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Purpose</th>
<th>Status</th>
<th>Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-1.001</td>
<td>General Regulations; Definitions</td>
<td>Clear up the definitions of certain terms, as well as to define “limited quantities” as used in ss. 499.01(3) &amp; (4), F.S.</td>
<td>4/10/15 – Rules workshop held.</td>
<td>Notice proposed rule based on industry input.</td>
</tr>
<tr>
<td>61N-1.010</td>
<td>Guidelines for Manufacturing Cosmetics</td>
<td>The rule adopts the federal guidelines for cosmetic manufacturing; the rule is necessary to bring Florida requirements in line with the federal guidelines.</td>
<td>4/24/15 – Responded to JAPC inquiry.</td>
<td>Notice of change based on JAPC comments.</td>
</tr>
<tr>
<td>61N-1.012</td>
<td>Records of Drugs, Cosmetics and Devices</td>
<td>Set forth recordkeeping requirements for Florida manufacturers engaging in “limited quantities” of Rx drugs obtained from non-Florida licensed entities.</td>
<td>4/10/15 – Rules workshop held.</td>
<td>Notice proposed rule based on industry input.</td>
</tr>
<tr>
<td>61N-1.013</td>
<td>Prescription Drugs; Receipt, Storage and Security.</td>
<td>Set forth Rx drug storage requirements for Florida manufacturers engaging in “limited quantities” of Rx drugs obtained from non-Florida licensed entities.</td>
<td>4/10/15 – Rules workshop held.</td>
<td>Notice proposed rule based on industry input.</td>
</tr>
<tr>
<td>61N-1.015</td>
<td>Licensing, Application, Permitting</td>
<td>Add language to incorporate updated licensing applications and to incorporate the application for the Restricted RX Drug Distributor-Blood Establishment permit.</td>
<td>2/20/14 – Notice of development published.</td>
<td>Draft language, including revised application forms, then file Notice of Proposed Rule</td>
</tr>
<tr>
<td>61N-1.020</td>
<td>Forms</td>
<td>Repeal of unnecessary rule.</td>
<td>Notice of repeal being drafted.</td>
<td></td>
</tr>
</tbody>
</table>

LICENSE EFFICIENTLY. REGULATE FAIRLY.
WWW.MYFLORIDALICENSE.COM
<table>
<thead>
<tr>
<th>61N-1.023</th>
<th>Restricted Prescription Drug Distributor Permits; Special Provisions</th>
<th>Create/set forth the restricted Rx drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)(1.c., F.S.</th>
<th>12/17/14 – Notice of Development filed</th>
<th>Draft language and file notice of proposed Rule</th>
</tr>
</thead>
</table>
61N-1.001 GENERAL REGULATIONS: DEFINITIONS
61N-1.001 General Regulations; Definitions.

(1) No change.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.0121(6), 499.0122(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)3., F.S., the management or owner of a permitted wholesale establishment has approved in writing 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 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 delivery the prescription drugs are delivered by the wholesaler directly to the ship/vessel or transfer possession to the appropriate ship/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 the number of transactions necessary for research and development purposes, the number of transactions necessary for research and development purposes to obtain a final FDA approval, or the number of transactions necessary for research and development purposes to obtain a final approval from a foreign regulatory authority; all transactions must be based on requirements set forth in the acquiring entity’s research and development records created contemporaneously with the research and development activities.

(on) “Pedigree” — means a document that satisfies the requirements of Section 499.003(13)(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.
“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.

“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.

“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.

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

“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 Biologies 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.

“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.

“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.

“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.

“Rx” – means prescription.

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

“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.

“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.

“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.

(ccaa) “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. Epoetin (epoetin alfa);
8. Gammune (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. Pangebulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mannanal 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. Zyptex (olanzapine).

(ddee) “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.

(eedd) “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.

(ffee) “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.

(geff) “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.

(hgge) “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.

(ih) “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.

(ji) “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(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. 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
NOTICE OF RULE CHANGE

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Division of Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:
61N-1.010 Guidelines for Manufacturing Cosmetics

Notice is hereby given that the following changes have been made to the proposed rule in accordance with Section 120.54(3)(d)1., F.S. published in Vol. 41, No. 60, March 27, 2015, issue of the Florida Administrative Register and are in response to written comments submitted by the Joint Administrative Procedures Committee staff:

1. Deleted reference to 499.002 in law implemented section.

2. Changed rule title to “Requirements for Manufacturing Cosmetics.”

3. 61N-1.010(2)(a) shall read:

   (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.)

4. 61N-1.010(2)(f) – deleted “adequate.”

5. 61N-1.010(3) shall read:

   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:

6. 61N-1.010(3)(c) shall read:

   (c) Constructed to ensure accurate measuring, mixing, and weighing operations;

7. 61N-1.010(3)(d) – deleted “where appropriate.”

8. 61N-1.010(4)(d) – deleted “appropriate.”

9. 61N-1.010(4)(e) – deleted “properly.”

10. 61N-1.010(5) – deleted “to ensure they conform to appropriate standards and specifications.”

11. 61N-1.010(5)(e) shall read:

   (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.

12. 61N-1.010(6)(a) – deleted “verify that it meets applicable chemical, physical, and microbiological specifications for quality.”

13. 61N-1.010(6)(b) – changed “should” to “shall” and deleted “appropriate.”

14. 61N-1.010(7)(c) – deleted “appropriate.”

15. 61N-1.010(7)(g) – deleted “meaningful.”

16. 61N-1.010(8) – changed “should” to “shall.”

17. 61N-1.010(8)(b) shall read:

(b) Returned cosmetics are examined for deterioration, contamination, and compliance with the manufacturer’s product development specifications.

Also, the phrase “product development” will be inserted immediately preceding “specifications” in 61N-1.010(8) in order to provide clarity and consistency between 61N1-1.010(8) and 61N1-1.010(8)(b).

18. 61N-1.010(9)(a) shall read:

(a) Internal audits are conducted randomly and on demand for a specific reason;

19. 61N-1.010(9)(c) shall read:

(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

20. 61N-1.010(9)(d) – deleted “satisfactory.”

21. 61N-1.010(10)(d) shall read:

(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.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 N. Monroe Street, Suite 26A, Tallahassee, Florida 32399-1047; Dinah.Greene@myfloridalegislature.com; 850.488.1802.
April 6, 2015

Mr. Reginald D. Dixon  
Executive Director  
Department of Business and Professional Regulation  
Division of Drugs, Devices and Cosmetics  
1940 North Monroe Street  
Tallahassee, Florida 32399-1047

Re: Department of Business and Professional Regulation  
Rule 61N-1.010, F.A.C.

Dear Mr. Dixon:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on March 27, 2015. I have the following comments.

Law Implemented: It does not appear that section 499.002 should be cited as a law implemented. See §§ 120.52(8), .536(1), Fla. Stat.

Title: Rule subsection (1) is being amended to state that this section is setting forth minimum requirements. Perhaps the department should consider revising the title of this rule to clarify that it is establishing requirements instead of guidelines.

61N-1.010: Please explain how these requirements are enforced. See Fla. Admin. Code R. 61N-1.024 (referring to rule section 61N-1.010 once in the rule establishing administrative enforcement).

61N-1.010(2)(a): Please explain what the department means by “suitable size, design, and construction.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.
Please explain what the department means by “adequate washing, cleaning, plumbing, toilet, and locker facilities.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “appropriate design, size, material and workmanship.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “suitable size and accuracy for measuring, mixing, and weighing operations.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “where appropriate.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “appropriate designated areas.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “properly supervised.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “appropriate standards and specifications.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “[p]roperly identified and controlled” and “meet acceptance specifications.” These terms appear to be vague and may not provide adequate standards for enforcement. They may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

Please explain what the department means by “applicable chemical, physical, and microbiological specifications for quality.” This appears to be
vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(6)(b): This paragraph contains a parenthetical, which states, “This system should be routinely cleaned and sanitized according to an appropriate standard operation procedure that ensures that no biofilm buildup.” It appears that the word “should” implies that the system may or may not be required to be cleaned and sanitized, which appears to vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat. Also, it appears that this sentence does not establish any ascertainable standards or criteria and may be impermissibly vague. See § 120.52(8)(d), Fla. Stat.

61N-1.010(7)(c): Please explain what the department means by “appropriate measures.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(7)(g): Please explain what the department means by “permanent meaningful, unique lot or control numbers.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(8): This paragraph provides in part that “the laboratory controls should include provisions to ensure ....” It appears that the word “should” implies that department may or may not require that the laboratory controls include provisions to ensure compliance with paragraphs (a) and (b). This also appears to vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(8)(b): Please explain what the department means by “compliance with acceptance specifications.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(9)(a): Please explain what the department means by regularly occurring audits. This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(9)(c): Please explain what the department means by “appropriate management, production, quality control, and lab personnel.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.
61N-1.010(9)(d): Please explain what the department means by “satisfactory completion.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

61N-1.010(10)(d): Please explain what the department means by “timely notification.” This appears to be vague and may not provide adequate standards for enforcement. It may also vest unbridled discretion in the department. See § 120.52(8)(d), Fla. Stat.

As always, please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

[Signature]

Marjorie C. Holladay
Chief Attorney

cc: Ms. Brittany B. Griffith
    Assistant General Counsel
April 22, 2015

Marjorie C. Holladay, Chief Attorney
Joint Administrative Procedures Committee
111 West Madison Street
Room 680 Pepper Building
Tallahassee, Florida 32399-1400

Re: Rule 61N-1.010, F.A.C.
Chapter 2012-61, Section 34, Laws of Florida

Dear Ms. Holladay:

Thank you for your correspondence dated April 6, 2015 regarding the above-referenced rule that was published in the Florida Administrative Register on March 27, 2015. The division’s responses to your specific questions are detailed below:

Law Implemented: The reference to 499.002 in the law implemented section shall be removed.

Title: The title of rule will be changed to "Requirements for Manufacturing Cosmetics."

61N-1.010: The provisions of 61N-1.024, F.A.C., set forth the severity and penalty ranges for violations of the statutes (Chapter 499, F.S.) and the rules (61N, F.A.C.). The division has an enforcement unit that investigates alleged violations of the division's statutes and rules. At the conclusion of the investigation, an investigative report is forwarded to the division's headquarters, where a determination is made as to whether sufficient evidence exists to formally take enforcement action against an entity for violation of the statutes and or rules. The division institutes enforcement action against entities, based on the severity of the violation, the actions taken by the person to correct the violations, and any prior violations. As 61N-1.024, F.A.C., current provides a severity and penalty range for violations of 61N-1.010, F.A.C., there is no need to amend this rule to account for the more extensive nature of the proposed changes.

61N-1.010(2)(a): The division will be filing a Notice of Change changing the verbiage of (2)(a) to the following:

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.)

61N-1.010(2)(f): The division will be filing a Notice of Change, deleting the word “adequate.”

61N-1.010(3): The division will be filing a Notice of Change, changing the verbiage of (3) to LICENSE EFFICIENTLY, REGULATE FAIRLY.

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the following:

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:

61N-1.010(3)(c): The division will be filing a Notice of Change, deleting the phrase “Of suitable size and” and changing the verbiage to the following:

Constructed to ensure accurate measuring, mixing, and weighing operations;

61N-1.010(3)(d): The division will be filing a Notice of Change, deleting the phrase “where appropriate.”

61N-1.010(4)(d): The division will be filing a Notice of Change, deleting the word “appropriate.”

61N-1.010(4)(e): The division will be filing a Notice of Change, deleting the word “properly.”

61N-1.010(5): The division will be filing a Notice of Change, deleting the phrase “to ensure they conform to appropriate standards and specifications.”

61N-1.010(5)(e): The division will be filing a Notice of Change, changing the verbiage of (5)(e) to the following:

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.

61N-1.010(6)(a): The division will be filing a Notice of Change, deleting the phrase “verify that it meets applicable chemical, physical, and microbiological specifications for quality.”

61N-1.010(6)(b): The division will be filing a Notice of Change, replacing the term “should” with “shall” and deleting the term “appropriate.”

61N-1.010(7)(c): The division will be filing a Notice of Change, deleting the word “appropriate.”

61N-1.010(7)(g): The division will be filing a Notice of Change, deleting the word “meaningful.”

61N-1.010(8): The division will be filing a Notice of Change, deleting the term “should” and replacing it with “shall.”

61N-1.010(8)(b): The division will be filing a Notice of Change, changing the verbiage of (8)(b) to the following:

Returned cosmetics are examined for deterioration, contamination, and compliance with the manufacturer’s product development specifications.

Also, in response to this comment, the division will be inserting “product
development" immediately preceding "specifications" in 61N-1.010(8) in order to provide clarity and consistency between 61N1-1.010(8) and 61N1-1.010(8)(b).

61N-1.010(9)(a): The division will be filing a Notice of Change, changing the verbiage of (9)(a) to the following:

Internal audits are conducted randomly and on demand for a specific reason;

61N-1.010(9)(c): The division will be filing a Notice of Change, changing the verbiage of (9)(c) to the following:

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

61N-1.010(9)(d): The division will be filing a Notice of Change, deleting the term "satisfactory."

61N-1.010(10)(d): The division will be filing a Notice of Change, changing the verbiage of (10)(d) to the following:

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.

I hope that this has been responsive to your inquiry.

Respectfully,

Reginald D. Dixon
Director

Attachment

cc: Mr. William N. Spicola, General Counsel
    Ms. Brittany B. Griffin, Assistant General Counsel
    Ms. E. Renee Alsobrook, Compliance Manager
61N-1.010 Guidelines Requirements for Manufacturing Cosmetics.

(1) All persons who manufacture or relabel label cosmetics in Florida must follow the minimum guidelines 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. Recordkeeping to document compliance with these guidelines is not mandatory, however, observation by an inspector of a deviation from these guidelines may constitute non-compliance with current good manufacturing practices.

(2) Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product.

(3) Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded.

(4) Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition.

(a) Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than contained laboratory animals). No domestic animals may be in the manufacturing areas.

(b) Sewage, trash, and other refuse or waste matter in and from the building and immediate premises shall be disposed of in a safe and sanitary manner.

(5) Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic.

(6) Container-closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product.

(7) An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

(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 subparagraph, “internal audit” means a systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether the 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 section, “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 cros 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 that ensure:

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 to safeguard against contamination.
(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 an established 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 specifically designed 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 499.013, 499.05 FS. Law Implemented 499.013, 499.008, 499.009. FS. History–New 7-1-96, Formerly 10D-45.0505, Formerly 64F-12.010, Amended .
61N-1.012 RECORDS OF DRUGS, COSMETICS AND DEVICES
61N-1.012 Records of Drugs, Cosmetics and Devices.

(1) through (16) No change.

(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Section 499.01(3) and (4)(b), F.S. and Rule 61N-1.001(2)(n), F.A.C., the required records must identify the requirements and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under 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, including, without limitations, Section 499.01(3) or (4)(b), and applicable federal laws.

Rulemaking Authority 499.003, 499.01(2)(g), 499.05, 499.0121 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.01212, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 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-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012, Amended 3-4-13, Amended
61N-1.013 PRESCRIPTION DRUGS; RECEIPT, STORAGE AND SECURITY
61N-1.013 Prescription Drugs; Receipt, Storage and Security.

(1) No change.
(2) No change.
(3)(a) through (c) No change.
(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 Section 499.01(3) and(4)(b), F.S. and Rule 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) through (7) No change.
61N-1.016 Product Registration.

(1) No change.

(2)(a) Applicants applying for an initial product registration of a product must:


2. No change.

3. No change.

4. No change.

(b) No change.

(3) PRODUCT REGISTRATION RENEWAL.

(a) Applicants applying for renewal of a product registration must:

1. Submit the DBPR form number DBPR-DDC-235, “Application for Product Registration Renewal,” Under Chapter 499, F.S., DOH-Form 1041, effective January 1999 March 2015, available at https://www.flrules.org/Gateway/reference.asp?No=Ref- 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 product registration’s expiration date.

2. No change.

3. No change.

(b) No change.

Rulemaking Authority 499.04, 499.015, 499.04, 499.05 FS. Law Implemented 499.01, 499.015, 499.04, 499.05. FS. History-New 7-1-96, Formerly 10D-45.0542. Amended 1-26-99, 4-17-01, 1-1-04. Formerly 64F-12.016.
61N-1.018 FEES
61N-1.018 Fees.

(1) Biennial fees for a MANUFACTURER or REPACKAGER permit are as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Drug Manufacturer</td>
<td>$1500</td>
</tr>
<tr>
<td>Prescription Drug Repackager</td>
<td>$1500</td>
</tr>
<tr>
<td>Device Manufacturer</td>
<td>$1200</td>
</tr>
<tr>
<td>Cosmetic Manufacturer</td>
<td>$800</td>
</tr>
<tr>
<td>Over-the-Counter Drug Manufacturer</td>
<td>$800</td>
</tr>
<tr>
<td>Compressed Medical Gas Manufacturer</td>
<td>$1000</td>
</tr>
<tr>
<td>Non-resident Prescription Drug Manufacturer</td>
<td>$1000</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>Category</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressed Medical Gas Wholesale Distributor</td>
<td>$600</td>
</tr>
<tr>
<td>Retail Pharmacy Drug Wholesale Distributor</td>
<td>$100</td>
</tr>
<tr>
<td>Freight Forwarder</td>
<td>$600</td>
</tr>
<tr>
<td>Veterinary Prescription Drug Wholesale Distributor</td>
<td>$1000</td>
</tr>
<tr>
<td>Limited Prescription Drug Veterinary Wholesale Distributor</td>
<td>$1000</td>
</tr>
</tbody>
</table>

(b) No change.

(3) Biennial fees for OTHER permits are as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Biennial Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complimentary Drug Distributor</td>
<td>$500</td>
</tr>
<tr>
<td>Veterinary Prescription Drug Retail Establishment</td>
<td>$600</td>
</tr>
<tr>
<td>Medical Oxygen Retail Establishment</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Blood Establishment</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Health Care Entity</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Charitable Organization</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Reverse Distributor</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Destruction</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Government Programs</td>
<td>$600</td>
</tr>
<tr>
<td>Restricted Prescription Drug Distributor – Institutional Research</td>
<td>$600</td>
</tr>
<tr>
<td>Third Party Logistics Provider</td>
<td>$600</td>
</tr>
<tr>
<td>Health Care Clinic Establishment</td>
<td>$255</td>
</tr>
</tbody>
</table>

(4) - (5) No change.

Rulemaking Authority 499.01, 499.04, 499.05, 499.831, 499.832 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.041, 499.05, 499.028, 499.831, 499.832 FS. History–New 7-1-96, Formerly 10D-43.0544, 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.
61N-1.027 Distribution of Emergency Use Medical Oxygen.

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

1. The permittee’s permit is current;

2. The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in section 499.90, F.S.;

3. The permittee creates, contemporaneously 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.; and

4. The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

Rulemaking Authority 499.85 F.S. Law Implemented 499.83, 499.85, 499.86, 499.89, 499.90 F.S. History-New
Limited Quantities Workshop Results
AGENDA

Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics Workshop
1940 N. Monroe Street
Board Room
Tallahassee, FL 32399

Conference Call Number 888-670-3525
Conference Code 9259887749

April 10, 2015
9:00 A.M. – 12:00 P.M.

DBPR Staff:
Reginald Dixon – Division Director
Renee Alsobrook – Compliance Manager
Dinah Greene – Government Operations Consultant II

TAB 1: Rule 61N-1.001 – General Regulations; Definitions
TAB 2: Rule 61N-1.012 – Records of Drugs, Cosmetics and Devices
TAB 3: Rule 61N-1.013 – Prescription Drugs; Receipt, Storage and Security
TAB 4: Statutory Language- Sections 499.01(3) & (4), F.S. (2014) provided:
TAB 5: Industry Correspondence –
a. Watson/Actavis
b. Vistapharm
c. Noven Pharmaceuticals
April 17, 2015

TRANSMITTAL VIA E-MAIL
AND HAND-DELIVERY

Ms. Dinah Greene, C.P.N.
Division of Drugs, Devices and Cosmetics
Department of Business and Professional Regulation
1940 North Monroe Street, Suite 26A
Tallahassee, Florida 32399-1047

Re: Follow-up Comments April 10, 2015, Limited Quantities Rule Workshop
Regarding Rules 61N-1.001 and 61N-1.012.

Dear Ms. Greene:

Thank you for allowing interested parties to submit further comments in response to the
April 10, 2015, limited quantities rule workshop regarding proposed Rules 61N-1.001 and 61N-
1.012. After having an opportunity to reflect on the comments and questions during the rule
workshop, Actavis, Inc. would like to present the following comments and proposed language
for the DDC Program’s consideration.

It is essential that the DDC Program understand that Actavis, and other drug
manufacturers following Good Manufacturing Practices ("GMP"), do not have real-time access
to all R&D quantities. By following GMP, Actavis has real-time access to clinical R&D
quantities.

In contrast, the industry standard for tracking of non-clinical/pre-clinical R&D quantities
is not as stringent as for clinical quantities and is often not done in real time. Rather, for non-
clinical/pre-clinical R&D quantities, the information is tracked on a manual basis, including
being manually entered in laboratory notebooks. Updating the records for non-clinical/pre-
clinical R&D quantities is much more of an onerous process. However, consistent with the
industry, the clinical quantities represent the majority of the API quantities at our site. For these
reasons, we respectfully offer the following alternative to the DDC Program’s proposed rule
61N-1.012(17) Records of Drugs, Cosmetics and Devices:
(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the required records must identify the requirements and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under 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, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

Additionally, from reading the DDC Program’s proposed rule 61N-1.012(17), it is our understanding that there are no requirements that reports actually be submitted. Rather, the proposed rule requires that the records be updated and kept on site.

Thank you again for the opportunity to provide comments in response to the April 10, 2015, limited quantities rule workshop. We look forward to continuing to participate in this important process.

Sincerely,

Ty Jackson
James T. Moore, Jr.
MEMORANDUM

To: Interested Parties

From: Reginald D. Dixon, Director

Date: March 16, 2015

Re: Rule Workshop – “Limited Quantities”

Pursuant to Chapter 2012-61, Section 34, Laws of Florida, the department is required to define “limited quantities” as that term is used in subsections 499.01(3) and 499.01(4)(b), Florida Statutes. The division proposes to define “limited quantities” in Rule 61N-1.001, by holding a workshop on April 10, 2015.

Attached are the PRIOR drafts of the proposed changes to Rules 61N-1.001, 6N1-.012, & 61N-1.013, F.A.C. This language is being put forth to start the discussion and IS NOT the final version.

The department is holding the workshop to obtain input from the industry regarding the rule language and to give the industry the opportunity to comment and submit any suggestions to improve upon the initial drafts provided.

Please submit any comments or proposed language by March 27, 2015 to: Dinah.Greene@myfloridalicense.com.
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-1.001: General Regulations; Definitions
61N-1.012: Records of Drugs, Cosmetics and Devices
61N-1.013: Prescription Drugs; Receipt, Storage and Security

The Division of Drugs, Devices and Cosmetics announces a workshop to which all persons are invited.
DATE AND TIME: April 10, 2015,
9:00 a.m. – 12:00 p.m.
PLACE: Department of Business and Professional Regulation
Board Room
1940 N. Monroe Street
Tallahassee, FL, 32399

888-670-3525 – Conference Call In #
9259887749 – Participant passcode

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Division proposes the rule amendments to clarify the definitions of terms set forth in Chapter 499, F.S., and the Division’s rules 61N-1.001, 61N-1.012 and 61N-1.013; set forth the records which must be created and maintained by entities in Florida engaging in the possession of limited quantities of prescription drugs, obtained from non-Florida licensed sources, for the purpose of research and development; and set forth the storage requirements for those entities.

A copy of the agenda may be obtained by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, 850-717-1802.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, 850-717-1802. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, 850-717-1802
March 5, 2015

Mr. Reginald D. Dixon
Executive Director
Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
1940 North Monroe Street
Tallahassee, Florida 32399-1047

Re: Mandatory Rulemaking
Chapter 2012-61, Section 34, Laws of Florida

Dear Mr. Dixon:

This is a follow-up to my previous correspondence regarding the above-referenced chapter law that mandates the department to implement rules. I understood from your response letter of February 2, 2015, that you did not intend to undertake rulemaking at this time because you anticipate the legislature may remove the requirement that the department define “limited quantities” by rule in section 499.01. Subsequent to your response, I understand that you advised the committee at its meeting on February 16, 2015, that the department intends to develop a rule and to notice a workshop to obtain input from regulated entities in order to start the rulemaking process. Please let me know as soon as possible when you expect a rule defining “limited quantities” will be formally proposed.

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

[Signature]

Marjorie C. Holladay
Chief Attorney

cc: Mr. William N. Spicola, General Counsel
Ms. Renee Alsobrook, Compliance Manager
Ms. Brittany B. Griffith, Assistant General Counsel

MC11:SA WORD/MARJORIE/MANDATORY RULEMAKING 2012-61,S.34,030515
March 7, 2015

Marjorie C. Holladay, Chief Attorney
Joint Administrative Procedures Committee
111 West Madison Street
Room 680 Pepper Building
Tallahassee, Florida 32399-1400

Re: Mandatory Rulemaking
Chapter 2012-61, Section 34, Laws of Florida

Dear Ms. Holladay:

Thank you for your correspondence dated March 5, 2015 (attached). As we discussed yesterday and in accordance with my representations to the committee, the division has noticed a rules development workshop for April 10, 2015. The purpose of the workshop is to allow the division to receive input from the regulated industry in developing a definition of "limited quantities" that does not adversely impact Florida-resident manufacturers and their ability to obtain the active pharmaceutical ingredient or finished dosage prescription drugs that they need to conduct research, teaching, and testing associated with bringing an FDA-approved drug to market. The timetable for actually publishing a proposed rule will depend heavily on the outcome of the rules workshop. Assuming that the workshop is successful and the division receives sufficient input to develop an appropriate definition of "limited quantities" I would expect that the division would be able to publish a notice of rule development by May 31, 2015.

I hope that this has been responsive to your inquiry.

Respectfully,

Reginald D. Dixon
Director

Attachment

cc: Mr. William N. Spicola, General Counsel
Ms. Brittany B. Griffin, Assistant General Counsel
Ms. E. Renee Alsobrook, Compliance Manager
TAB 1: Rule 61N-1.001-General Regulations; Definitions
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 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.S., the management or owner of a permitted wholesale establishment has approved in writing a document that is available for inspection under Section 499.054, 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 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 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 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 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.

(pq) “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.

(qe) “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.

(qf) “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.

(qg) “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.

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

(qi) “Propagation” of a drug – means, as used under the definition of “manufacture” at Section 499.003(37), 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 Biological 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.

(qj) “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.

(qk) “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.

(q1) “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.

(q2) “Rx” – means prescription.

(q3) “Sale” – includes any transfer of title or ownership whether by barter, exchange or gift.

(q4) “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.

(q5) “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.

(q6) “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.

(q7) “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.

(Specify drug) — means all dosage forms, strengths and container sizes of the following prescription drugs:

1. Benica (valdecoxib);
2. Celebrex (celecoxib);
3. Combivir (lamivudine/zidovudine);
4. Crizivir (indinavir sulfate);
5. Difucan (fluconazole);
6. Epivir (lamivudine);
7. Epogen (epoetin alfa);
8. Gamimmune (globulin, immune);
9. Gamvagard (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. Parglobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mammalian derived);
22. Suziva (efavirenz);
23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
24. Venoglobulin (globulin, immune);
25. Viara (sildenafil citrate);
26. Vider (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Zidov (abacavir sulfate);
31. Zocor (simvastatin);
32. Zofig (ondansetron);
33. Zeladex (goserelin acetate); and
34. Zyproxa (olanzapine).

(ddee) “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.

(cedd) “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.

(ffe) “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.

(pegf) "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.

(hheg) "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.

(ii) "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.

(ii) "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.
TAB 2: Rule 61N-1.012- Records of Drugs, Cosmetics and Devices
61N-1.012 Records of Drugs, Cosmetics and Devices

(1) Through (16) No Change

(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the required records must forecast, identify and schedule the acquisition and use of each such drug relative to anticipated and ongoing R & D activities. These records must be created in advance of or contemporaneously with the particular R & D activities, and are subject to inspection under Section 499.051, F.S. Nonclinical/preclinical R & D quantity forecasts must be updated at least monthly and clinical R & D quantity forecasts must be updated at least quarterly. These records must account for all product acquired and consumed in R & D activities, and the researcher must ensure that none of the product acquired for R & D is used in any clinical (for use on or in humans) context or setting. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.
TAB 3: Rule 61N-1.013- Prescription Drugs; Receipt, Storage and Security
61N-1.013 Prescription Drugs; Receipt, Storage and Security.

(1) Through (2) No Change.

(3)(a) Through (c) No Change.

(d) Facility requirements for the storage and handling of prescription drugs.

1. through 2. No change.

3. Prescription drugs obtained in "limited quantities: for research and development ("R & D") purposes under Section 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) Through (7) No change.

TAB 4: Statutory Language-Sections 499.01(3) & (4), F.S. (2014) Provided
Sections 499.01(3) & (4), F.S. (2014) provide:

(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 in limited quantities 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), but not the requirements of s. 499.01212. 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 department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption. 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. 499.0051(14), and a knowing failure is a violation of s. 499.0051(4).

(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.
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), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of 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. The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

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.

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), but not the requirements of s. 499.01212.

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 ss. 499.0121(6) and 499.01212 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 prescription drug wholesale distribution license, permit, or registration number; 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(4).

(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.
TAB 5: INDUSTRY CORRESPONDENCE

A. WATSON/ACTAVIST
B. VISTAPHARM
C. NOVEN PHARMACEUTICALS
A. Tim Moore, Gray Robinson- Attorneys at Law Watson/Actavist
June 28, 2013

TRANSMITTAL VIA E-MAIL AND HAND-DELIVERY

Ms. Dinah Greene, C.P.N.
Division of Drugs, Devices and Cosmetics
Department of Business and Professional Regulation
1940 North Monroe Street, Ste. 26A
Tallahassee, FL 32399-1047

Re: Comments to Notice of Proposed Rulemaking Regarding Rules 61N-1.001 and 61N-1.012

Dear Ms. Greene:

Thank you for the opportunity to comment on the proposed amendments to Rules 61N-1.001 and 61N-1.012. Our law firm represents Watson Laboratories, Inc.-Florida ("Watson"). Watson’s ultimate parent, Actavis, Inc., operates in 62+ countries, serves over 5 billion customers, and is the third-largest generic manufacturer in the world. Actavis has publicly announced plans to invest over $40 million to expand its manufacturing and warehousing operations in Florida. Indeed, R&D and manufacturing operations critical to the continued success of Actavis, Inc. are housed under Watson, which employs approximately 1,250 Floridians in three facilities in Broward County.

Over the last several years Actavis, Inc. and Watson have worked hard to establish strong relationships with Florida stakeholders, as well as its regulator, the Drugs, Devices and Cosmetics ("DDC") Program. Watson was actively involved in passing legislation creating the limited permit and pedigree exemptions at issue in this rule development. These exemptions were meant to enhance and facilitate research and development of generic pharmaceuticals in Florida, while still protecting the public from harmful or adulterated drug product. They are found in Florida Statute Sections 499.01(3) and 499.01(4)(b), and provide license and pedigree exemptions for the distribution of "limited quantities" of active pharmaceutical ingredient ("API") and finished product, respectively, for R&D purposes.
I. Amendments to Rule 61N-1.001

The Department proposes to define limited quantities in Rule 61N-1.001 as follows:

(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.

It is critical the DDC Program understand that the proposed definition of limited quantities will inhibit the ability of Watson, and other drug manufacturers with operations in Florida, to compete against similar companies located in other states and around the world. Although it appears the DDC Program intended to allow flexibility in the importation of drug product for R&D purposes by limiting quantities purchased to that needed for a particular timeframe, the rule as drafted will serve as an impediment.

For nonclinical and preclinical research and development, a manufacturer may only import a 3-month supply of drug product. For the clinical phase of research and development, a manufacturer may only import a 6-month supply. By necessity, companies engaging in research and development of generic drugs must move quickly
and aggressively in order to compete in the marketplace. Oftentimes this race results in drug manufacturers filing an Abbreviated New Drug Application the very day that a name brand product is launched.

Importantly, at the beginning of the R&D process, generic manufacturers will almost always order the entire amount of drug substance/product needed for all phases of R&D. This happens for two reasons: (1) if only part of the needed drug substance/product is purchased, a subsequent shortage in product would bring the entire R&D process to a halt; and (2) if drug substance/product is ordered in batches, and a competing generic manufacturer learns of the orders, the competitor will often attempt to buy up the remaining available volume – this is a well-known tactic in the industry. Accordingly, the rule as drafted would have the unintended effect of codifying a competitive disadvantage in the marketplace for generic manufacturers engaging in R&D in the State of Florida.

We suggest that the proposed rule be amended to allow manufacturers to import the entire amount of drug substance/product needed to engage in specific R&D for a particular generic product. Accordingly, we respectfully offer the following alternative:

(n) “Limited quantities” – pursuant to Section 499.01(3) and (4)(b), F.S., means the number of transactions necessary for R&D purposes and/or to obtain a final FDA approval and/or approval from an equivalent foreign regulatory authority, based on requirements set forth in R&D records created contemporaneously with the R&D activities.

This proposed alternative definition of “limited quantities” will ensure Florida manufacturers engaging in R&D remain vibrant and competitive in the marketplace. Furthermore, the DDC Program remains empowered to police the integrity of the drug supply and maintain the safety of the public because these same manufacturers must still adhere to, recordkeeping, and product segregation requirements set forth in Florida Statutes Chapter 499 and Rule Chapter 61N-1.

II. Amendments to Rule 61N-1.012

The Department proposes to add a paragraph (17) to Rule 61N-1.012, which reads as follows:

61N-1.012 Records of Drugs, Cosmetics and Devices.
(17) For purposes of prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.0012(n), F.A.C., the required records must forecast, identify and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under Section 499.051, F.S. Nonclinical/preclinical R&D quantity forecasts must be updated at least monthly, and clinical R&D quantity forecasts must be updated at least quarterly. These records must account for all product acquired and consumed in R&D activities, and the researcher must ensure that none of the products acquired for R&D is used in any clinical (for use on or in humans) context or setting. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

We respectfully offer the following alternative:

(17) For purposes of prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.0012(n), F.A.C., the required records must identify the requirements and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under Section 499.051, F.S. R&D quantities for all phases must be updated at least annually. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

It is critically important that any confidential R&D documents obtained by the DDC Program pursuant to its inspection authority under Florida Statute Section 499.051 remain confidential and exempt from disclosure under Chapter 119 as trade secret information. We believe Section 499.051 clearly provides such protection but its importance cannot be stressed enough, and we urge the DDC Program to ensure that its inspectors and attorneys are adequately trained on this subject matter. The inadvertent,
improper disclosure of confidential, trade secret R&D-related information could cost a Florida company millions of dollars.

Thank you for the opportunity to provide comments to the proposed rule amendments. We look forward to continuing to participate in this important process.

Sincerely,

Timothy M. Cerio

TMC/jfl
B: John Lay, Director, RA/QA- Vistapharm
Good Afternoon,

Thank you for the opportunity to comment on the proposed amendments to Rules 61N-1.001 and 61N-1.012. VistaPharm Inc., is a small generic pharmaceutical company located in Largo, Florida. While VistaPharm only has 88 employees we continue to grow and continue to hire new employees that live here in the state of Florida. The reason we continue to grow is due to our Research and Development program for generic pharmaceutical products. As the Director or Regulatory Affairs and Quality Assurance I also assign activities to a three person R&D group. As written the rule will force VistaPharm to eliminate the three person team and move our R&D program to a out of state third party. FDA requires generic companies to provide stability studies on three different finished product lots which requires up to three drug substance batches.

As per ICH Q1A Stability Testing of New Drug Substance and Products:

2.2.3. Selection of Batches

Data from stability studies should be provided on at least three primary batches of the drug product. The primary batches should be of the same formulation and packaged in the same container closure system as proposed for marketing. The manufacturing process used for primary batches should simulate that to be applied to production batches and should provide product of the same quality and meeting the same specification as that intended for marketing. Two of the three batches should be at least pilot scale batches and the third one can be smaller, if justified. Where possible, batches of the drug product should be manufactured by using different batches of the drug substance.

FDA requires at least two different batches of the active ingredient with justification or three different batches of drug substance without justification. The majority of API producers require most companies to purchase a minimum quantity of drug substance no matter the amount needed. VistaPharm’s R&D program has products that require less than 1Kg of drug substance to produce a single lot of drug product, however, the drug substance producer requires VistaPharm to order no less than 3 kg’s of a single lot of drug substance. Therefore, VistaPharm is left with 2 kg’s that will basically remain in storage until the drug application is approved. At that time the API will be tested and if passed at testing used in commercial distribution. This product is a FDA rated “AA” product that requires no human studies. As written this program could not be conducted here at VistaPharm and would have to be moved to an out of state third party.
It appears that the state has information that believes that pharmaceutical companies have millions and millions of extra R&D monies to waste on extra quantities of API just sitting in isolation. I can assure the state that is not the case. If this rule as written becomes law VistaPharm will be forced to eliminate R&D personnel, move R&D out of state and will cost the state of Florida millions to its economy.

Thank you for the opportunity to provide comments to the proposed rule amendments. We look forward to continuing to participate in this process.

Sincerely,

John G. Lay
Director, RA/QA
VistaPharm Inc.
(727) 530-1633
Dear Ms. Greene,

On behalf of Noven Pharmaceuticals, Inc., please see the attached correspondence regarding proposed amendments to Rules 61N-1.001 and 61N-1.012.

Thank you for your attention.

Alina Bowman  
Sr. Coordinator – Corporate Affairs  
Noven Pharmaceuticals, Inc.  
11960 SW 144th Street  
Miami, Florida 33186  
Direct: 305-964-3182  
abowman@noven.com  
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April 2, 2015

Ms. Dinah Greene, C.P.N.
Division of Drugs, Devices and Cosmetics
Department of Business and Professional Regulation
1940 North Monroe Street, St. 26A
Tallahassee, FL 32399-1047

Subject: Proposed Rulemaking Regarding Rules 61N-1.001 and 61N-1.012

Dear Ms. Greene:

I am writing on behalf of Noven Pharmaceuticals, Inc. ("Noven") with regard to the proposed amendments to Rules 61N-1.001 and 61N-1.012.

By way of background, Noven is a Florida-based developer, manufacturer and marketer of prescription pharmaceuticals. Noven was founded in South Florida 28 years ago, and currently employs over 350 persons in Florida and over 550 nationwide. All of our manufacturing operations are located in Florida. We are not large by industry standards, but in our specialty areas, we believe we have made a meaningful difference in the lives of patients in the State of Florida and across the U.S. In order to continue to do so, it is critical that we remain competitively positioned and not unduly constrained with regard to access to active pharmaceutical ingredients and finished products, respectively, for R&D purposes.

In that regard, we would like to express our endorsement and strong support for the opinions and positions expressed in the letter to the Division dated June 28, 2013, from Gray Robinson on behalf of Watson Laboratories, Inc. (copy attached). Noven shares the view expressed in the Gray Robinson letter that the proposed amendments, as drafted, will inhibit the ability of drug manufacturers with operations in Florida to compete against similar companies located in other states and around the world, and supports the alternative language proposed in the letter.

Thank you for taking time to consider our view on this matter.

Sincerely,

[Signature]

Steven M. Dinh
Vice President & Chief Scientific Officer
Noven Pharmaceuticals, Inc.

Attachment