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

June 10, 2015
9:00 A.M. – 10:00 A.M.

DBPR Staff:
Reginald Dixon – Division Director
Renee Alsobrook – Compliance Manager
Dinah Greene – Government Operations Consultant II
Brittany Griffith- General Counsel

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: Gray Robinson – Correspondence
TAB 5: April 10, 2015 – Rule Workshop Minutes
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics

RULE NO.: RULE TITLES:
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: June 10, 2015, 9:00 a.m. - 10:00 a.m.
PLACE: Department of Business and Professional Regulation, Professions Board Room, 1940 N. Monroe Street,
Tallahassee, FL, 32399

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;
F.A.C. 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.

Limited Quantities: [Paragraph 61N-1.001(2)(n), F.A.C.]

(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.

Records of Drugs: [Subsection 61N-1.012(17), F.A.C.]

(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 within 30 calendar days of the particular R&D
activities, and are subject to inspection under Section 499.051, F.S. Non-clinical/pre-clinical R&D quantities must
be updated annually, and clinical quantities must be updated semiannually. The researcher must maintain all other
records required under Chapter 499, including, without limitations, Section 499.01(3) or (4)(b), F.S. and applicable
federal laws.


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.
A copy of the agenda may be obtained by contacting: Dinah Greene at The Division of Drugs, Devices and
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.
PROPOSED NEW LANGUAGE
Limited Quantities: [61N-1.001(2)(n), F.A.C.] 

(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.

Records of Drugs: [61N-1.012(17)]

(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 within 30 calendar days of 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.

Storage & Security: [61N-1.013(3)(d)3.]

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.
TAB 1: Rule 61N-1.001-General Regulations; Definitions
6IN-1.001 General Regulations; Definitions.

(1) No change.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.012(1)(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 6IN-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)(11)(d), F.S., the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under Section 499.051, F.S., at the time of the inspection, the physical absence of the designated representative from the permitted establishment, pursuant to the written policy developed and maintained by the owner or management of the permitted establishment, for a cumulative period not to exceed 60 calendar days in any 12-month period for situations such as: the birth of the employee's child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the care of a family member (child, spouse, or parent) with a serious health condition, where the employee is needed to care for the a family member (child, spouse or parent) with a serious health condition, or the employee's own serious health condition makes the employee unable to perform the functions of the designated representative.

(d) "Authorized recipient" means a person permitted by or otherwise authorized by Florida law, or by the law of the jurisdiction in which the person receives the prescription drugs, Chapter 499, F.S., to purchase, receive or possess those prescription drugs. The term includes:

1. Any a pharmacy licensed under 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.

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 deliver the prescription drugs are delivered by the wholesaler directly to the ship/vessel or transfer possession to the appropriate ship's/vessel's officer as near to the ship/vessel as state and federal laws allow.

(e) "Broker" means a person participating in a prescription drug the wholesale distribution by (i) buying, purchasing, or otherwise taking ownership of or title to the drug, (ii) selling or transferring, or offering to sell or transfer, ownership of or title to the drug, (iii) to a person other than the patient or the patient's agent—without taking physical possession of the drug or 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.

(i) 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 biostrudies 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.

(par) "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.

(par) "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.

(par) "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.

(par) "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.

(par) "Product" — anything produced or made either naturally or artificially.

(par) "Propaganda" 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 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.

(par) "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.

(par) "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.

(par) "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.
(par) "Rx" — means prescription.
(par) "Sale" — includes any transfer of title or ownership whether by barter, exchange or gift.
(par) "Separate and distinct cosmetic product" — means a cosmetic product for that establishment which is, or will be sold,
distributed, or given away. The addition of color, flavor, or scents does not make a separate and distinct cosmetic product for each
variation.
(par) "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.
(par) "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.
(par) "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.

(4b) “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. Crizaline (crizanlida-sulfate);
5. Diflucan (fluconazole);
6. Epivir (lamivudine);
7. Epopgen (epoetin alfa);
8. Gammune (globulin, immune);
9. Gammagard (globulin, immune);
10. Immune globulin;
11. Lamictal (lamotrigine);
12. Lipitor (atorvastatin calcium);
13. Lupron (leuprolide acetate);
14. Neupogen (filgrastim);
15. Nutropin AQ (somatropin, e-coli derived);
16. Pangeglobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Receptin (ceftiraxone sodium);
21. Sarostim (somatropin, mammalian-derived);
22. Sustiva (efavirenz);
23. Trizivir (abacavir-sulfate/lamivudine/zidovudine);
24. Venogobulin (globulin, immune);
25. Viagra (sildenafil citrate);
26. Videx (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Ziden (abacavir-sulfate);
31. Zocor (simvastatin);
32. Zofran (ondansetron);
33. Zoledex (p.o.sorcin acetate); and
34. Zyprexa (olanzapine).

(ddes) “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.

(fee) “Usual course of business as carriers” – means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes:

1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR s. 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and,
2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 61N-1.012(1), (2), F.A.C., apply to all distributions of prescription drugs under this sub-sub paragraph. In all such distributions to commercial airlines, the recipient’s license number shall be the registration number assigned to the carrier by the Federal Aviation Administration.

(ggff) “Valid client-veterinarian relationship” — means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

(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.

(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.

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

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

Rulemaking Authority 499.003(31), 499.024, 499.025(5), 499.013(3), 499.014(4), 499.014(6), 499.012(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, 499.061, 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, 1-30-83, 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.
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 Rule 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.

Rulemaking Authority 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 F.S. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 F.S. 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.
TAB 3: Rule 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)(a), 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.

STATUTORY LANGUAGE

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. 499.005(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.
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:

www.gray-robinson.com
(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.
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES, AND COSMETICS

IN RE: RULE NO. 61N-1.001,
RULE NO. 61N-1.012,
RULE NO. 61N-1.013

RULE WORKSHOP

April 10th, 2015
9:00 a.m. - 9:33 a.m.
1940 North Monroe Street
Board Room, Northwood Centre
Tallahassee, Florida

Reported by:

SCHEDULE WOODS, COURT REPORTER
For the Record Reporting, Inc.
1500 Mahan Drive - Suite 140
Tallahassee, Florida, 32308
PRESENT

REGINALD DIXON
(DIVISION DIRECTOR)

RENEE ALSOBROOK
(COMPLIANCE MANAGER)

DINAH GREENE
(GOVERNMENT OPERATIONS CONSULTANT)

* * *

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA
850 222 5491 STATE OF FLORIDA
PROCEEDINGS

MR. DIXON: Good morning, everyone. This is Reginald Dixon. I'm the Division Director for the Drugs, Devices, and Cosmetics Division. We're going to go ahead and start. It's a little bit after 9:00 o'clock this morning. Today is April 10th, 2015.

Just from a preliminary basis, we have a court reporter here in the room, and so for those of you on the phone and even those of you who are in the room, if you would like to make a comment, it would be very appreciated if you all would state your name and the company that you represent so that we have a clear record on the rulemaking that goes forward from here.

Just to -- kind of an introduction, again, my name is Reginald Dixon. I'm Division Director. Renee Alsobrook is also here from the Division, as well as Dinah Greene, who has been working with us on a lot of our rules. I guess we'll just go ahead and get started unless anyone wanted to make appearances for the record.

(No response.)

All right. The purpose for this workshop this morning is that a couple of years ago, our
legislature passed a statute which authorized manufacturers here in Florida to obtain limited amounts of API, as well as finished product for research and development purposes.

The department initially tried to develop a rule which we thought would allow the industry to continue to do business as they were, but also give the department the ability to do inspections and also ensure that the folks are actually importing and receiving limited amounts of prescription drugs.

We had some comments from that on that rule and so we withdrew the rule and wanted to come back to you all, to the industry, to the folks who would actually be affected by this rule, for you all to give us input on exactly how it is that you think this rule should operate, the language that you would like to see, so that we could hopefully put something together that would both serve the purpose of the statute, as well as not hinder Florida businesses or put you all at a disadvantage.

If you open up the agenda materials, what you'll see -- I'm sorry. The first tab that you have is the version that deals with -- it shows
you the notice, the letter that we received on
March 5th from the Joint Administrative Procedures
Committee, as well as my letter back to them on
March 7th.

But it also has a tab where it says
61N-1.001, which is our general definitions. And
the initial language that we had proposed for that
to define "limited quantity" is actually included
there. Once we -- and I didn't necessarily want
to go through all of the languages, unless someone
here wanted to do that.

We also, in addition to the trying to define
"limited quantities," we also tried to define or
put the recordkeeping requirements in there, and
also, at Tab 3, the storage and security
requirements.

In response to that, we did get several
letters. One of the letters, I believe that
several folks have commented on, both either to me
or in writing, was more in support of the initial
letter that we received from Watson or Actavis.
Watson gave a thorough explanation of why it is
that they felt that the language would be
detrimental for companies here in Florida and
respectfully requested some changes to that
language.

And so other than the response that we have from Watson, we have not had anyone else to provide the department with any type of substantiative feedback which would help the department develop language. And so what we are seeking today is input from the industry which would give the department some guidance on language that would be both workable, and also, that would allow the industry to continue to operate at a high level.

So what I would like to do, unless someone has any objection, I would like to open it up to the floor for input from anyone who, whether in the room or on the phone, who would like to have some comment.

I could tell you from a departmental standpoint, one thing that would help us is for someone in the industry to give us an idea of exactly what it is and how the process works for them to bring a product to market so that as we try to come up with language, we could keep that in mind as we develop language going forward.

MR. DRAKE: Good morning. My name is Paul Drake. I'm speaking on behalf of Noven
Pharmaceuticals as a qualified representative.

I passed out a addition to the Noven
Pharmaceuticals letter that is on the very last
page of the agenda packet. I just wanted to add a
couple of extra comments. Obviously, I'm here
representing Noven and I wanted to assert Noven's
position.

We strongly agree with the letter that was
written by Watson Laboratories -- well, it was
written on behalf of Watson Laboratories -- for
several reasons. First of all, in short, the
rules can't be "one size fits all." Instead,
rules must be flexible enough to allow generic
research and development companies the freedom to
perform R&D in the way that keeps them competitive
in the workplace -- in the global marketplace.

For example, in the proposed rule, it's --
and in several of the rules previously, proposed
amendments, it stated timeframes for the ability
of -- for limited quantities, anywhere from 30
days to 3 months to 6 months, and that's just not
necessarily how the industry works.

The -- some -- for example, some research and
development projects can last a year, two years,
three years, and my client's even said up to eight
years for some companies and some products.

And to limit them to only being able to purchase a three-month supply or even a six-month supply is a severe handicap, because sometimes they just can't project exactly how long they're going to be working on a certain project. They need to buy all of their API at the same time so they get the best -- they get a consistent batch.

Also, this is how it works in the industry:

If a competing company finds out that they're working on a product, they'll attempt to buy up the volume. So it's very important for -- if you want to stay competitive when you're developing these generic drugs, that you are able to buy as much -- all the API that you need or that you can foreseeably need. And so we agree with the Watson amendments that strike the language of the supply, the three-month whatnot, written on Page 3 of the -- of the Watson letter.

Also, we agree with Watson's second rule change regarding -- regarding recordkeeping. It's extremely important that under, of course, for the DDC program, any confidential -- or any documents obtained we -- we strongly suggest and we recommend that they remain confidential and exempt
from disclosure under Chapter 119 as trade secret information.

Any inadvertent or improper disclosure of confidential trade secret information could cost an R&D company potentially millions of dollars. So once again, we agree with the Watson Pharmaceuticals amendment to the -- to the rule change there.

And we just think that the rules as -- the rule changes, as stated, submitted by DDC would could potentially cost millions of dollars and hundreds, if not thousands, of jobs in Florida due to handicapping companies like Noven, like Watson, and others from being competitive in the global marketplace. Thank you very much.

MS. ALSOBROOK: Mr. Drake, before you leave, what was your recommendation on the recordkeeping requirement? I think the initial rule had monthly and quarterly. What's the recommendation from Noven as to maintaining records?

MR. DRAKE: We agree with the Noven recommendation on Page 4 of the -- the Watson recommendation on Page 4 of their -- their letter. Their alternative, we agree with that alternative. We also agree with their alternative for the
limited quantities on Page 3, their language for
that one as well.

MS. ALSOBROOK: And do you have any comment
as to why a period of every six months or
quarterly would be too burdensome to the industry?

MR. DRAKE: Well, like I said earlier, it's
just very difficult to determine whether -- like,
how much product you need at any specific time.
Like, if they could only purchase up to three
months, there's a good -- there's a chance that
that active pharmaceutical ingredient could either
have a shortage or competing companies could find
out that they're trying to develop that drug, and
therefore, purchase the rest of the -- the API of
that specific drug that's on the market, therefore
handicapping our client and every other company
that does this as well.

So it's good to just be able to allow them to
purchase in bulk for as long as they need, while
still maintaining, obviously, recordkeeping
requirements. They're going to be open to, you
know, share the information with the DDC, of
course --

MS. ALSOBROOK: As long as we can make sure
that that -- the trade secret --
MS. DRAKE: Of course.

MS. ALSOBROOK: -- is maintained?

MR. DRAKE: Absolutely. Thank you.

(Whereupon, Exhibit No. 1 was marked for identification.)

MR. DIXON: Did anyone else have any comments that they would like to make at this point?

(No response.)

One of the questions I would like to ask -- this is a follow-up to the question asked by Ms. Alsobrook. With regards to recordkeeping, the division, at one point, had draft language that required monthly updating and quarterly updating. And I know Mr. Drake spoke a little bit towards supporting the Watson proposition that those records only be updated annually.

Does anyone in the room or anyone in the audience, can anyone speak to exactly why updating your recordkeeping, the records that you have, quarterly or bi-annually versus annually would be burdensome to their clients or to their business?

(No response.)

Okay. With regards to the requirement for the storage, the department proposed language
which basically said that any product that was received pursuant to this chapter -- pursuant to these provisions, that those products had to be physically segregated from all other products intended for manufacturing, compound, dispense, or administration and in the manufacturer's establishment. These drugs also had to be stored and maintained separate and clearly -- in a clearly designated area.

Does there anyone on the phone or anyone in the room here have any comments as to whether or not those requirements would be overly burdensome on them or their clients? Okay.

MR. YUDAN: Michael Yudan, Actavis Pharmaceuticals.

I'd like to ask clarification regarding the -- your understanding of whether quantities are to be updated at least annually or quarterly. Are you referring to R&D-branded quantities that we use for -- I'm sorry, for branded products that we use for R&D development and for new projects, or are you talking about updating the inventory annually and making sure that the quantities that you bring in match the quantities that are in your inventory?
MR. DIXON: I'm sorry, say that one more time.

MR. YUDAN: Yeah. I'm not exactly sure your question regarding -- where you're taking -- the question about whether or not quantities should be updated quarterly.

MS. ALSOBROOK: We're looking at the letter written on behalf of Actavis -- Watson/Actavis by Mr. Serio back in 2013. And it's Paragraph 17, and it's on Page 4 of that letter.

MR. YUDAN: Okay.

MS. ALSOBROOK: Paragraph 17 specifically. You see, it's like Line 3 of the proposed rule where the recommendation was "updated at least annually." It says specifically, "These records must be created in advance of or contemporaneously with particular R&D activities and are subject to" -- I'm sorry -- "and are subject to inspection under Section 499.051, Florida Statute. R&D quantities for all phases must be updated at least annually." That was the proposal that was set forth on your behalf.

MR. YUDAN: Right.

MS. ALSOBROOK: It's my understanding that that would be your records and the quantity left,
or the amount you're holding for R&D, would be
updated annually. We're asking specifically if it
would be a burden for you to update the amount of
API you're holding for R&D quarterly or
semi-annually?

MR. YUDAN: I guess what I can say is that
the -- since we're a GMP facility, which is we
follow good manufacturing practices that maintain
an inventory -- and actually live --

MS. ALSOBROOK: Yes.

MR. YUDAN: -- is what is followed. So we
follow annually inherently in the fact that we are
a GMP facility. And we -- it's more of a sort of
live sort of exercise, so the inventory is always
live. Does that make sense?

MS. ALSOBROOK: Yes, it does. And I guess
that's why we're asking, because if you're
following the GMP procedure, it seems like almost
daily, you know what your inventory is.

So I guess what I'm trying to understand, as
the Chief of Enforcement, if I came into your
facility and asked you on any day, what is your
current inventory of API, I would expect that you
would know that as a good manufacturer.

I'm just not trying to make you generate a
record, so that's what I'm trying to learn from you, how would I find that out? I mean, if you ordered 1,000 kilos for your research project to go eight years and I come in there in year two, I would want to know, how much do you have?

But I don't want to inflict upon you some silly recordkeeping requirement if you can produce that in some manner. So is there some GMP terminology that you could give me that I could insert into a record-keeping requirement?

If you could write -- I mean, I hope the director would leave the record open so that you can come back and think about something that you could tell us that's consistent within the industry that we could put into a recordkeeping requirement so I don't generate some document that you've got to write.

That's the purpose of the workshop, so that I can learn what the industry would call that document. And we could come in and say, oh, well, they've used "X" amount of these developments in their inventory of 100,000 kilograms or 8 kilograms is down to "X", based upon what they've used. You understand where I'm trying to go?

MR. YUDAN: I understand.
MS. ALSOBROOK: Thank you.

Did I confuse everybody else or was I successful? No. Good.

Brittany, did I get you all confused since you've got to help me?

Now, back to the director's question about separation, is that still okay with everybody? You could maintain a separation of your research and development drugs from others?

MR. DIXON: Did anybody have any comments on that at all? The reason we're asking, truthfully, and what we're looking for is we're looking for input from the industry. And what we would hope is that we would get input, so that once we wrote the language, we would avoid necessarily having to have a rule challenge and having to go through all of this again.

So that is why -- that is one of the reasons for having this -- this type of an open discussion where we could gather information from folks. So it's almost like voting. If you don't vote, you can't complain about the person that you -- get elected. Does anyone have any concern about the requirement that you keep the API segregated?

MR. DRAKE: Paul Drake again.
When you say "physically segregated," how would that -- how would that be? Would it just have to be in a separate locker? Would it just be, kind of like, a separate area of a shelf? I mean, how strenuous is this going to have to be?

MR. DIXON: Generally speaking, sort of like a quarantine area in the sense that it's just got to be a separate area of your facility where you designate, this is the API for research and development.

MR. YUDAN: Could it possibly be in the same room as others?

MR. DIXON: I do not believe that we have -- that this draft would require a separate room or anything. The only thing that we're always looking for when we go in, from an enforcement perspective, is that you have it clearly designated and separated.

MS. ALSOBROOK: I think that the other thing in the room was probably the previous rule's use of the term "transactions." I'm understanding from all of you that that is something that we just can't use in the rule, the number of transactions.

If you looked at the prior draft, they have
used -- let me go to the previous draft real quick. I'll read just quickly. "Limited quantities, non-clinical, pre-clinical for purposes of non-clinical research and development, the number of transactions necessary to advance the program to a clinical stage, provided that the researcher may not acquire or have on hand one of the three-months supply of any product." And it goes on.

That phraseology is not consistent with industry practices. Is that what I understand from the comments we've been receiving? Can anybody speak to that?

Good deal. Thank you. One more time for the record, give us your name.

MR. YUDAN: Michael Yudan, Actavis Pharmaceuticals.

Can I get some clarification on your question again?

MS. ALSOBROOK: Well, I think that when the draft was written, the thought was, because we aren't manufacturers, that maybe you just ordered API periodically throughout the research project, and that periodically, through the process, you ordered API and those were transactions. That's
the phrase we were, I think, using. I'm gathering
that that is not the case, that you order API for
the entire project; is that correct?

MR. YUDAN: That's correct.

MS. ALSOBROOK: Okay. And not to lead you,
because as a lawyer, I would do that, but is that
to maintain the consistency in the API that you
use for the project, as well as to keep other
competitors from obtaining the API? Or what is
the basis for ordering a bulk of the API for the
research project?

MR. YUDAN: Those two are also reasons, but
there are other reasons besides that. The -- one
of the reasons, in addition to the other two that
you just mentioned, was that it takes a long time
to synthesize the API.

So when we start a project, a generic project
actually has a shorter duration from start -- from
inception of the project to the actual submission
of the ANDA to the FDA than a branded product
does, so we have a shorter time to develop and
submit.

And obtaining -- in some cases, the API takes
months to synthesize. So we want to obtain as
much API as we can IN the beginning so we know we
don't have to have that synthesize -- the
synthesis -- they don't have to synthesize later
down the road, which would impact the timeline.

The other thing is variability. So there is
lot-to-lot variability. So in order for us to
reduce the variability, you want to order all of
one lot as much as we can in the beginning so we
could reduce that variability down the road
because we --

MS. ALSOBROOK: That -- okay. That, I
understand. Okay. Thank you. Thank you very
much.

MR. DIXON: Okay. One more time, does anyone
else have any other comments that they would like
for the department to consider with regards to the
definition of "limited quantities," any of the
recordkeeping requirements, or the storage
requirements that are proposed, or anything that
you would allow -- that you at least want the
department to consider in going forward? As it
goes forward, we're trying to put language
together on these rules.

MR. RUSSELL: I have a general question or
comment. My name is Joey Russell. I'm with
Nephron Pharmaceuticals.
MR. DIXON: Go ahead, Mr. Russell.

MR. RUSSELL: It seems that the -- and I'm just -- I'm assuming these things. I don't know them. But it seems like the original intent of the language in Chapter 499 was to provide exemptions for non-permitted entities to distribute materials within the state.

And I'm just wondering if -- because in 499, section (3), it's the exemption for a non-resident prescription drug manufacturer. And (4)(b), it has to do with a -- distributing limited quantities, again, in the states from an establishment located in the United States to an establishment -- anyway, it's a -- it's a way to control non-permitted entities from distributing drugs in the state.

I'm wondering if now, with the passage of the Drug Quality and Securities Act and the permitting requirements that are outlined within it, if maybe the -- maybe the thinking on the topic has changed at all?

MR. DIXON: I think that I -- well, let me put it this way: I understand your question but I do not believe that the answer to your question is relevant to the actual -- the rule workshop, in
the sense that I understand that you're saying
that there may be some additional licensing
requirement because the DQSA has implemented it
and it may require licensing, whereas, other folks
may have thought it exempted licensing.

But the truth of the matter is Florida
Statutes have not changed, and unless and until
they do, then we've got a legal obligation to try
to go forward with developing a rule that allows
companies to actively engage with the possession
of these products or these substances. I won't
say "products," because "products" is a DQSA term
now.

But we have to try to come up with a rule
that gives meaning to our statute. So unless and
until our statutes have changed -- I know that's a
long answer -- that's a long non-answer to your
question, but it would not be a good idea for us
to try to give you, you know, legal interpretation
of what the requirements of DQSA are and how they
impact these exemptions set up under 499.01.

MR. RUSSELL: Okay, that's a fair response.
And my comments then on the -- on the "limited
quantities" language -- and I can only look at
this from a manufacturer because that's the --
that's the environment that I'm in.

But from our perspective, we have -- we have
so many recordkeeping requirements that we have to
meet in terms of the -- just the federal
requirements and the GMP requirements, the
additional layers of recordkeeping, I think, is
what we get hung up on from time to time.

So I think our general recordkeeping
practices -- and it sounds like the other comments
previously alluded to this as well -- our normal
and our standard recordkeeping requirements for
commercial products would seem to be adequate for
the kinds of information that you're looking for.

MR. DIXON: Thank you.

Does anyone else have any comment about the
recordkeeping requirements? We're not going to
hold you guys to the comments. We're just -- we
really are just looking for input from the
industry. We're not going to tie you down, that
you told us to this so you have to follow it.

MR. YUDAN: Mike Yudan again.

We agree with the statements that was just
made. Yeah.

MR. DIXON: Okay. Did anyone else have any
comments at all regarding the drafts that are
available for you, or anything else that you would
like the department to consider going
forward? Going once.

(No response.)

Okay. Well, as always, I guess if you all
have some more comments that you subsequently
develop after having had some time to think about
this, we would ask that you submit those to our
office, to Ms. Greene, I guess we could say by --
what we would like to do is leave this record open
for a week. That would be until next Friday, 5:00
o'clock next Friday, April 17th, to submit
additional submissions.

If you have additional language, or
additional comments, or anything else that you
would like for the department to consider, forward
those documents to Ms. Greene, and what we'll do
is we'll attach those to the record of these
proceedings, and we will use that and we will
consider that information going forward.

Otherwise, I guess we will conclude this
workshop. Thank you, everybody.

(Whereupon, the proceedings were concluded at
9:33 a.m.)

* * *

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA
850 222 5491 STATE OF FLORIDA
CERTIFICATE OF REPORTER

STATE OF FLORIDA  
COUNTY OF LEON  

I, SCHEDALE L. WOODS, Court Reporter and  
Notary Public, do hereby certify that the foregoing  
proceedings were taken before me at the time and place  
therein designated; that my shorthand notes were  
thereafter translated under my supervision; and the  
foregoing pages numbered 3 through 24, are a true and  
correct record of the aforesaid proceedings.  

I FURTHER CERTIFY that I am not a relative,  
employee, attorney or counsel of any of the parties,  
nor relative or employee of such attorney or counsel,  
or financially interested in the foregoing action.  

Dated this 10th day of April, 2015.

SCHEDALE L. WOODS  
FOR THE RECORD REPORTING  
1500 Mahan Drive, Suite 140  
Tallahassee, FL 32308  
(850)222-5491
DDC Rule Workshop
April 10, 2015

Noven Pharmaceuticals, Inc., affirms the view of Watson Laboratories in their letter to the DDC, regarding changes to Rules 61N-1.001 and 1.012, F.A.C. The DDC’s proposed definition of limited quantities will inhibit the ability of R&D drug manufacturers in Florida, like Noven, to compete against similar companies located in other states and around the world. The DDC’s proposed rule changes will have the unintended effect of codifying a competitive disadvantage in the marketplace for generic manufacturers engaging in R&D in the State of Florida.

In short, the Rules cannot be one size fits all. Instead, the rules must be flexible enough to allow generic drug R&D companies the freedom to perform R&D in the way that keeps them competitive in the global marketplace.

Provisions that limit the amount of active pharmaceutical ingredients supply to any time limit will be a severe handicap, as the industry does not operate on such strictly defined timetables. Some R&D projects last as long as 8 years, and enough API must be purchased at the beginning of the process to last the length of that project. Furthermore, if a company orders product in batches, and a competing generic manufacturer learns of the orders, the competitor will often attempt to buy up the remaining available volume.

Noven also agrees with Watson’s second rule amendment. It is critically important that any confidential R&D documents obtained by the DDC Program, pursuant to its inspection authority under Section 499.051, F.S., remain confidential and exempt from disclosure under Chapter 119 as trade secret information. Any inadvertent or improper disclosure of confidential, trade secret information could cost and R&D company millions of dollars. This will again handicap companies like Noven and Watson, with the potential to put thousands of Floridians out of work.

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