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

Conference Call Number 888-670-3525
Conference Code 9259887749

December 1, 2016
9:30 a.m.

Council Members:
Steve Mays, Chair, Prescription Drug Wholesalers
Jeenu Phillips, Vice Chair, Board of Pharmacy
Primary Prescription Drug Wholesalers
Brian Flies, Retail Pharmacy
Michael Mone, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Arlene Elliott, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Vacant, Physician

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, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor

Call to Order: Steve Mays, Chair

TAB 1: Chair's Report – Steve Mays, Chair
a. Drugs, Devices and Cosmetics Inspection Process
b. Discuss Drug Supply Chain Security Act Update for the February Meeting

TAB 2: Division Director's Report – Reginald Dixon
a. DDC Rules

TAB 3: August 18, 2016 – Meeting Transcript

TAB 4: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
The Division of Drugs, Devices and Cosmetics, Drug Wholesale Distributor Advisory Council announces a telephone conference call to which all persons are invited.
DATE AND TIME: December 1, 2016, at 9:30 a.m.
PLACE: (888) 670-3525; Conference Code 9259887749
GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business
A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047; or (850) 717-1800. Dinah.greene@myfloridalicense.com
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: . 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, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, FL 32399-1047; or (850) 717-1800. Dinah.greene@myfloridalicense.com
I. First type of inspection is:

ROUTINE/COMPLIANCE INSPECTION—section 499.065, Florida Statutes states that notwithstanding s. 499.051 (Inspection and Investigation authority), the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules.

The department shall have the right of entry and access to these facilities as any reasonable time.

499.065 Inspections; imminent danger.—
(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(2) To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Business and Professional Regulation or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3) The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public’s health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.
(4) For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.
History.—s. 23, ch. 2003-155; s. 6, ch. 2004-328; s. 6, ch. 2006-92; s. 107, ch. 2008-6; s. 34, ch. 2008-207; s. 6, ch. 2012-143.

II. The second type of inspection is:

INVESTIGATIVE/COMPLAINT INSPECTION—section 499.051, Florida Statutes authorized agents of the department to inspect, and investigate any establishment permitted pursuant to this chapter during business hours for the purpose of enforcing this chapter (499), chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

In addition to the authority above, the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter (499) and rules adopted under this chapter regarding any drug, device, or cosmetic product.

499.051 Inspections and investigations.—
(1) The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter during business hours for the purpose of enforcing this chapter, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.
(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or cosmetic product.
(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter and rules adopted under this chapter constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.
(4) Any application for a permit made pursuant to s. 499.012 or s. 499.831 and rules adopted under those sections constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter and the rules adopted by the department to administer this chapter, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.
(5) The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.
(6) The authority to inspect under this section includes the authority to secure:
(A) Samples or specimens of any drug, device, or cosmetic; or
(b) Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.
(7)(a) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed.
(b) Information that constitutes a trade secret, as defined in s. 812.081, contained in the complaint or obtained by the department pursuant to the investigation must remain confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution as
long as the information is held by the department. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

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

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; s. 5, ch. 86-133; s. 11, ch. 88-159; ss. 37, 52, ch. 92-69; s. 199, ch. 94-218; ss. 3, 5, 8, ch. 94-309; s. 7, ch. 95-366; s. 332, ch. 96-406; s. 240, ch. 99-8; s. 62, ch. 2003-1; s. 21, ch. 2003-155; s. 26, ch. 2007-6; s. 29, ch. 2008-207; s. 8, ch. 2014-89; s. 11, ch. 2016-6; s. 13, ch. 2016-212.

III. The third type of inspection is:

NEW BUSINESS, CHANGE OF LOCATION, CHANGE OF OWNER INSPECTION—section 499.012, Florida Statutes and Rule 61N-1.015, Florida Administrative Code provide the requirements for permits. The inspection is conducted to confirm the facility meets the requirements for the permit and the information supplied on the application is accurate.

PROCEDURE DURING INSPECTION

With any type of inspection the Drug Inspector:

1. Introduces themselves;
2. Presents to the Firm, the Firm’s Bill of Rights. The Firm’s rights are:
   "As a licensee with DBPR, you have the right to:
   Know the reason for your inspection
   Have knowledge, helpful, objective and courteous inspectors
   Have professional inspectors who use safe and minimally disruptive practices in completing your inspection
   Receive a copy of the completed inspection
   Question the findings of your inspection
   Ask for reconsideration of those findings
   Be efficiently and fairly treated in all dealings with DBPR

Our Commitment
We will diligently work to make Florida and DBPR great places to conduct business every day. In keeping with this purpose, we will treat our licensees as valued customers and partners, invest in our employees, and uphold laws that protect the public and enhance Florida’s competitiveness.

Your inspection today will be conducted by:______________

If you have any concerns about your inspection, it is your right to speak directly to our regional manager, Mary Mayleben at (727) 518 3183 to address your questions and to receive a timely response.***

If you presser to submit your inquiry online, contact us @ myvoice@myfloridalicense.com
Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact the office by phone or by traditional mail."

**For several inspectors the contact is Renee Alsobrook at (850) 717-1804, instead of Dr. Mayleben.

3. Advise as to the type of inspection.  (If investigative, the Inspector may not be as informative.)
4. Request an area to meet with Firm's staff and for Inspector to work if available.
5. Discussion with Firm- any changes with company from last inspection, advise as to documents needed, determine how documents are stored, how maintain records so Inspectors know how to ask for the records-if stored on site, electronic or paper, ask that documents be gathered.  The discussion depends on facility size and responses.
6. Inspector asks who will assist with inspection.
7. Inspector reviews the electronic inspection form with Firm-goes over the yes and no questions on inspection form.
8. Inspector requests a tour/observes the Firm —to look at security, quarantine area, storage, other statutory and rule requirements.  During the tour, the Inspector may determine additional documents need to be requested such as policy and procedures to determine if Firm is following their policy and procedure.
9. Request documents.
10. After tour, review documents, records, policy and procedures.
11. Inspector asks follow up questions from tour and regarding documents.
12. Inspector discusses inspection document with Firm —provides Firm opportunity to read and review inspection and sign inspection form.
13. Inspector obtains Firm’s exit statement.
TAB 1:  Chair’s Report – Steve Mays, Chair

b. Discuss Drug Supply Chain Security Act Update for the February Meeting
To: Drug Wholesale Distributor Advisory Council  
From: Reginald D. Dixon, Director  
Date: November 16, 2016  
Re: Division Rulemaking (rev. 11/16/16)

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>Define terms set forth in recent changes to Chapter 499, F.S. that became effective 7/1/16.</td>
<td>Effective 10/10/16</td>
<td>N/A</td>
</tr>
<tr>
<td>61N-2.003</td>
<td>Application for Device Manufacturer Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.007</td>
<td>Application for Limited Prescription Drug Veterinary Wholesale Distributor Permit</td>
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<tr>
<td>61N-2.011</td>
<td>Application for Nonresident Prescription Drug Manufacturer Permit</td>
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<tr>
<td>61N-2.0111</td>
<td>Application for Nonresident Prescription Drug Manufacturer – Virtual Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Rulemaking filed 10/20/16; JAPC comments received 10/27/16; Notice of Correction published 11/17/16; DDC Response sent 11/17/17.</td>
<td>File Notice of Change re: JAPC comments.</td>
</tr>
<tr>
<td>61N-2.012</td>
<td>Application for Out-of-State Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.0111</td>
<td>Application for Nonresident Prescription Drug Manufacturer – Virtual Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Rulemaking filed 10/20/16; JAPC comments received 10/27/16; Notice of Correction published 11/17/16; DDC Response sent 11/17/17.</td>
<td>File Notice of Change re: JAPC comments.</td>
</tr>
<tr>
<td>IN-2.015</td>
<td>Application for Prescription Drug</td>
<td>To adopt and incorporate the division’s permitting</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File Notice of Change re: JAPC comments.</td>
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<tr>
<td>Item</td>
<td>Description</td>
<td>Action</td>
<td>Additional Information</td>
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<td>61N-2.0111</td>
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<td>To adopt and incorporate the division's permitting application forms into rule.</td>
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<td>File Notice of Change re: JAPC comments.</td>
</tr>
<tr>
<td>61N-2.016</td>
<td>Application for Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division's permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>Finalize draft of application; File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.017</td>
<td>Application for Prescription Drug Wholesale Distributor – Broker Only Permit</td>
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<tr>
<td>61N-2.018</td>
<td>Application for Restricted Rx Drug Distributor – Blood Establishment Permit</td>
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<td>61N-2.019</td>
<td>Application for Restricted Rx Drug Distributor – Charitable Organization Permit</td>
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<td>61N-2.020</td>
<td>Application for Restricted Rx Drug Distributor – Destruction Permit</td>
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<tr>
<td>61N-2.021</td>
<td>Application for Restricted Rx Drug Distributor – Government Programs Permit</td>
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<tr>
<td>61N-2.022</td>
<td>Application for Restricted Rx Drug Distributor – Health Care Entity Permit</td>
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<tr>
<td>61N-2.023</td>
<td>Application for Restricted Rx Drug Distributor – Institutional Research Permit</td>
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<tr>
<td>61N-2.024</td>
<td>Application for Restricted Rx Drug distributor – Reverse Distributor</td>
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<tr>
<td>61N-2.025</td>
<td>Application for Retail Pharmacy Drug Wholesale Distributor Permit</td>
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<tr>
<td>61N-2.026</td>
<td>Application for Third Party Logistics Provider Permit</td>
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<tr>
<td>61N-2.027</td>
<td>Application for Veterinary Prescription Drug Retail Establishment</td>
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<tr>
<td>61N-2.028</td>
<td>Application for Veterinary Prescription Drug Wholesale Distributor Permit</td>
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</tbody>
</table>
November 17, 2016

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

Re: Department of Business and Professional Regulation
Rule 61N-2.0111, F.A.C.

Dear Ms. Holladay:

Thank you for your correspondence dated October 27, 2016 (attached). Before I endeavor to address the specifics of your correspondence, I wanted to clarify the nature of the correspondence. As you are aware, section 120.54(3)(d), Florida Statutes, provides in part:

"Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee."

Your correspondence does not indicate that the committee is proposing to object to the rule, thus the department is treating your comments as "written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action." If the intent of your correspondence was to notify the department of proposed committee objections, please advise as such so that we can appropriately update the department’s files. The department’s responses to the items you commented on are:

Summary of Statement of Estimated Regulatory Costs and Legislative Ratification

The department’s determination that a statement of estimated regulatory costs was not necessary was based on the department’s analysis of the impact the proposed rules in light of the statutory factors set forth in section 120.541, F.S. The department’s analysis was conducted by the division and subjected to an extensive, thorough vetting process, before ultimately being approved by the agency head.

Note: Although the proposed rule establishes a new permit, for which a $1,000 biennial application fee is charged, the proposed rule does not increase any regulatory costs for entities impacted by the proposed rule. Currently, entities that engage in activities falling under this permit are required to obtain a nonresident prescription drug manufacturer permit. The fee for that permit is $1,000 biennially. The new nonresident prescription drug manufacturer - virtual permit removes some of the physical establishment requirements pertaining to storage of prescription drugs that that are placed on nonresident prescription drug manufacturers.

LICENSE EFFICIENTLY, REGULATE FAIRLY.
WWW.MYFLORIDALICENSE.COM
The department filed a Notice of Correction with respect to the summary included with the notice of this rule; the Notice of Correction published today.

The department will add section 499.05, F.S., to the rulemaking authority.

The department will add sections 499.05 and 559.79, F.S., to the law implemented.

It appears that the reference to Rule 61N, F.A.C. instead of "Rule Title 61N, F.A.C." is technical in nature; thus the division will update this at the time of filing the rule for adoption.

DBPR-DDC-236:
Page 1:
The department is aware of Op. Att'y Gen. Fla. 75-293 (1975), but interprets this opinion in a manner slightly different from the manner. The department believes that this opinion stands for the premise that once the department has begun processing the application, the department has earned the fee and that fee is due to the department, and absent a statutory provision specifically authorizing the department to refund the fee, the department is prohibited from doing so. This is supported by the fact that numerous other professions housed within the department have statutes that specifically state which fees are refundable and which fees are nonrefundable. Usually, the statutes provide that initial application fees are nonrefundable and initial licensure fees are refundable. This makes sense as the department expends resources processing applications whether the applicant is qualified and received the license for which the applicant applied. Where the applicant is not qualified and does not receive the license, it seems that the initial licensure fees are nonrefundable. The division's fees are not split out, thus, unless the fees fall under the provisions of section 215.08, F.S., they are nonrefundable, absent a statute to the contrary.

Pages 4, 5, and 6:
The department will be filing a Notice of Change amending the form. The form will amended to include a disclosure statement with respect to the department’s use of Social Security Numbers. The disclosure statement that will be added is:

The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a)f, 499.012(8)(o), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.

Section 499.012(4)(a)f., F.S., authorizes the division to collect “[a]ny other relevant information that the department requires.” The department believes that this authorizes the department to request the date of birth of these individuals as well as the FEID/FEIN numbers of business entities owning 10 percent or more of the outstanding stock or equity interest.
I hope that the department’s responses have addressed your comments. The department will be filling the Notices of Changes as indicated above later this week. If you have any questions or concerns please give me a call at the number listed above.

Respectfully,

Reginald D. Dixon
Director

Attachment(s):
October 27, 2016 Letter
October 27, 2016

Mr. Reginald D. Dixon
Executive Director
Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
2601 Blairstone Road
Tallahassee, Florida 32399-1047

Re: Department of Business and Professional Regulation
Rule 61N-2.0111, F.A.C.

Dear Mr. Dixon:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on October 20, 2016. I have the following comments.

Summary of Statement of Estimated Regulatory Costs and Legislative Ratification:
This proposed rule establishes a new permit, for which a $1,000 biennial application fee is charged. Please explain how the department determined that a statement of estimated regulatory costs is not required for this rule.

Summary: The summary of this proposed rule states, “The proposed rules adopt and incorporate the division’s permitting applications for resident and nonresident virtual prescription drug manufacturer permits and nonresident prescription drug repackagers.” It does not appear that proposed rule 61N-2.0111 pertains to virtual prescription drug manufacturer permits or to nonresident prescription drug repacker permits. Please publish a notice of correction that correctly summarizes this proposed rule.
Rulemaking Authority: It appears that section 499.05 should be cited as rulemaking authority.

Law Implemented: It appears that section 499.05 and section 559.79 should be added as laws implemented.


This rule incorporates by reference form DBPR-DDC-236, Application for Permit as a Nonresident Prescription Drug Manufacturer – Virtual, effective July 2016.

DBPR-DDC-236:
Page 1: Please explain why the form states that the $1,000 biennial application fee is nonrefundable. Absent statutory authority to the contrary, it appears that if an applicant requests a refund of this fee prior to any action being taken concerning the applicant’s qualifications, the fee should be refundable. See Op. Att’y Gen. Fla. 75-293 (1975). It does not appear that section 499.041(1)(a), which authorizes this fee, states that the application fee is nonrefundable.

Pages 4, 5, and 6: These pages request the social security numbers and dates of birth of each owner, partner, member, manager, officer, director, chief executive or other person who directly controls the operation of the business entity, as well as of the social security numbers and dates of birth of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. The form also requests the FEID/FEIN if the person owning 10 percent or more of the outstanding stock or equity interest is a business entity. It appears the request for these social security numbers is asked pursuant to section 559.79(1).

Please include a written statement on the form that complies with section 119.071(5)(a)2., which requires each agency to state in writing the purpose for the collection of an individual’s social security number. Also, although not a matter within the purview of this committee, you should be aware that the Federal Privacy Act of 1974, Dec. 31, 1974, Pub. L. No. 93-579, section 7, 88 Stat. 1896, 1909, codified at 5 U.S.C. section 552a, also governs the disclosure of social security numbers.

Please explain which statute cited as a law implemented authorizes the department to request the date of birth of these individuals.
Please explain which statute cited as a law implemented authorizes the department to request the FEID/FEIN of the business entities owning 10 percent or more of the outstanding stock or equity interest.

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. Renee Alsobrook
Chief of Compliance and Enforcement
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Nonresident Prescription Drug Manufacturer - Virtual</td>
<td>□ $1,000 nonrefundable biennial application fee. If the applicant is applying for multiple manufacturing permits in the applicant’s name and at applicant’s address, you are only required to pay for the permit that has the highest fee.</td>
</tr>
<tr>
<td></td>
<td>□ Make cashier’s check, corporate check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>□ If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>□ Submit photocopy of your license/permit(s) issued by your resident state that authorizes the distribution of prescription drugs from the applicant’s establishment’s address.</td>
</tr>
<tr>
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<td>□ Sign and date the Affidavit section of the application.</td>
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<tr>
<td></td>
<td>Mail completed application to: Department of Business and Professional Regulation Division of Drugs, Devices and Cosmetics 2601 Blair Stone Road Tallahassee, FL 32399-1047</td>
</tr>
</tbody>
</table>

PLEASE NOTE:

- Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.

- The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a)(f), 499.012(8)(c), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.
State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Nonresident Prescription Drug Manufacturer - Virtual
Form No.: DBPR-DDC-236

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3346/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3346/1020]

Current Permit Number: ____________________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN: ____________________________

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name: ____________________________

FICTIONS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations). This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

__________________________________________

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:

__________________________________________
**APPLICANT MAILING ADDRESS**

Street Address or P.O. Box:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
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</thead>
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</tbody>
</table>

Country (if located outside the United States):  Telephone Number:  Fax Number:

**PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED**

*(only if different from mailing address) Check ☐ if not applicable*

Street Address:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Country (if located outside the United States):  Telephone Number:  Fax Number:

**APPLICATION CONTACT**

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

Last/Surname:  First:  Middle:  Suffix:

Address:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tr>
</tbody>
</table>

Telephone Number:  Fax Number:

**E-Mail Address:**

**EMERGENCY CONTACT INFORMATION**

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

Last/Surname:  First:  Middle:  Suffix:

Position/Title:

Street Address:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Telephone Number:  E-Mail Address:
### OPERATING HOURS

List the establishment’s daily hours of operation in terms of Eastern Time. REMEMBER to circle “a.m.” or “p.m.” for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to</th>
<th>a.m./p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td></td>
<td>Fri</td>
</tr>
<tr>
<td>Tue</td>
<td></td>
<td>Sat</td>
</tr>
<tr>
<td>Wed</td>
<td></td>
<td>Sun</td>
</tr>
<tr>
<td>Thu</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section III – Ownership Information

#### TYPE OF OWNERSHIP

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other:

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

#### List the state of incorporation or organization:

- [ ] State:

#### Name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

#### Address:

- [ ] Street Address:
- [ ] City:
- [ ] State:
- [ ] Zip Code (Optional):

#### List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th>#</th>
<th>Name &amp; Title</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
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<tr>
<td>----------------</td>
<td>-------</td>
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<td></td>
</tr>
<tr>
<td>3. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
</tr>
<tr>
<td>4. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
</tr>
<tr>
<td>5. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
</tr>
<tr>
<td>6. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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</tr>
<tr>
<td>7. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
</tr>
<tr>
<td>8. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
<td></td>
</tr>
</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. If such person is a business entity, list the business entity name, FEID/FEIN and percentage of ownership and check the box labeled "N/A" for date of birth.

1. Name: | SSN/FEID/FEIN# | Date of Birth: | % of Ownership: |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

2. Name: | SSN/FEID/FEIN# | Date of Birth: | % of Ownership: |
<table>
<thead>
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<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
<td>% of Ownership:</td>
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<td>----------------</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
<td>% of Ownership:</td>
</tr>
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<td>Street Address:</td>
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<td>Zip Code:</td>
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<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
<td>% of Ownership:</td>
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<td>Zip Code:</td>
</tr>
<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box □ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). □ Yes □ No

Parent Company Name | % of Ownership

---

DBPR-DDC-236 - Application for Permit as a Nonresident Prescription Drug Manufacturer - Virtual
Incorporated by rules: 61N-2.0111, F.A.C.
Eff. Date: July 2016
Page 7 of 15
Is diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care services provided at the address of the establishment that is the subject of this permit application? If so, please list the name of the company/companies providing such services below and provide the corresponding license or permit number(s) issued by your residing state's regulatory authority. (Use additional sheet(s) if necessary).  

<table>
<thead>
<tr>
<th>Name:</th>
<th>Permit/License No.:</th>
<th>Issuing Agency:</th>
</tr>
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**Section IV – Background Questions**

**BACKGROUND QUESTIONS**

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

If you answer “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

1. **Yes** ☐  **No** ☐  Has the applicant or any "affiliated party" (defined above) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?

2. **Yes** ☐  **No** ☐  Has the applicant or any affiliated party (defined above) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?

3. **Yes** ☐  **No** ☐  Has the applicant or any affiliated party (defined above) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?

4. **Yes** ☐  **No** ☐  Has the applicant or any affiliated party (defined above) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?

5. **Yes** ☐  **No** ☐  Has the applicant or any affiliated party (defined above) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?

6. **Yes** ☐  **No** ☐  Has the applicant or any affiliated party (defined above) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address).
Section V – Explanation(s) for “Yes” response(s) to background question(s)

<table>
<thead>
<tr>
<th>EXPLANATION</th>
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</table>

Section VI – Other Permits or Licenses

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there any permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant’s establishment or address? (If yes, please provide a list of all such permits including the issuing agency, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no other permits or licenses.).</td>
</tr>
<tr>
<td>□ Permit/license list provided.</td>
</tr>
<tr>
<td>□ No permits/licenses.</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

| 2. Is the applicant licensed or permitted to manufacture prescription drugs at the location of the establishment by the licensing or permitting authority in the state where the establishment is located? |
| □ Yes – Resident license attached. |
| □ No – Not permitted in resident state. |
| □ No – Not permitted and not required to be permitted in resident state; written explanation attached with a copy of relevant regulation and/or laws showing that no permit is required. |
| □ Yes □ No |

| 3. Is the applicant licensed in any other state as a manufacturer, repackager, distributor, or wholesale distributor of prescription drugs? (If yes, please provide a list all such permits including the state, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no other permits or licenses.). |
| □ Permit/license list provided. |
| □ No permits/licenses. |
| □ Yes □ No |
4. Does or will the applicant sell prescription drugs into Florida? (If no, provide the name and address from which the drugs are sold into Florida in the spaces provided below. Use additional sheets if needed.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Physical Address</th>
<th>Florida Permit/License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
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</tbody>
</table>

5. Provide information on the establishment(s) that will ship or physically transfer prescription drugs, for which the applicant is considered the manufacturer, into or in Florida on the applicant establishment's behalf.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Florida Permit/License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
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</tr>
</tbody>
</table>

**Section VII – Prescription Drug Manufacturing Activity**

**MANUFACTURING ACTIVITIES**

Generally identify the applicant's intended customers, the persons and entities that will purchase or receive prescription drugs from the applicant establishment after permit issuance.

- [ ] Manufacturers
- [ ] Hospitals
- [ ] Veterinarians
- [ ] Other (explain)

- [ ] Wholesalers
- [ ] Practitioners
- [ ] Pharmacies
- [ ] Health Care Clinics

Identify the types of prescription drugs that will be distributed by this virtual manufacturer establishment for which this establishment is considered the manufacturer.

- [ ] Human Prescription Drugs
- [ ] Veterinary Prescription Drugs
- [ ] Solid Dose
- [ ] Liquids (Oral)
- [ ] Injectable
- [ ] Topical
- [ ] Dental
- [ ] Ophthalmic
- [ ] Compressed Medical Gases
- [ ] Repackage – From Bulk as the manufacturer, not as a repackager
- [ ] Repackage – From Stock as the manufacturer, not as a repackager
- [ ] Refrigerated (Human, Veterinary, API or Otherwise)
- [ ] Frozen (Human, Veterinary, API or Otherwise)

- [ ] Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):
  - [ ] Manufacturers
  - [ ] Pharmacies for Compounding
  - [ ] Other explain

Controlled Substances: Provide your DEA Number: ___________________ or check [ ] No DEA Number

Check Schedules: [ ] Sch II [ ] Sch III [ ] Sch IV [ ] Sch V
Identify type of operation.

| ☐ | FDA Drug Application Holder (e.g. NDA, ANDA, BLA, NADA, ANADA holder) | ☐ | Co-licensed partner of the FDA Drug Application Holder | ☐ | Own Label Manufacturer |

Provide your Federal Food and Drug Administration (FDA) establishment registration number.

☐ FDA Establishment Registration Number: ____________________________

or

☐ No FDA Establishment Number AND a written explanation is attached ☐.

1. Are prescription drugs to be distributed under this permit intended for export? (Note: A permit may be required for Florida recipients that are freight forwarders handling prescription drugs in Florida.)

☐ Yes ☐ No

2. Do you manufacture a prescription drug as a finished product? (If no, explain on a separate sheet providing accurate details and provide an example of a typical label.)

☐ Yes ☐ No

3. Does the applicant establishment intend to distribute prescription drug samples in the State of Florida through its agents, employees, or independent contractors? (If yes, a Complimentary Drug Distributor permit is required. Please review sections 499.01 and 499.028, Florida Statutes.)

☐ Yes ☐ No

4. Will all required records be stored and maintained at applicant's physical address? (If no, provide the name and address of the establishments where all required records will be stored and maintained under question #4a.)

☐ Yes ☐ No

4a. Name and physical address where required records will be stored:

Name: ____________________________

Street Address: ____________________________

City: ____________________________ State: ____________________________ Zip Code (+4 optional): ____________________________

5. Will the required records be computerized, automated or stored electronically?

☐ Yes ☐ No

If yes, will you have a back-up procedure to be able to provide required records?

☐ Yes ☐ No

If electronically stored and not maintained as a scanned image, is the electronic data maintained unchanged from the time of creation, receipt, purchase or distribution, depending on the document type?

☐ Yes ☐ No

6. Section 499.0121(2), F.S., requires establishments to be equipped with a) an alarm system to detect entry after hours and b) a security system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. Please provide a written description of the alarm and security systems that includes both the type of systems used and how the systems are monitored.

Alarm system description included? ☐ Yes ☐ No

Security system description included? ☐ Yes ☐ No

7. Sections 499.01(2)(a)1. and 499.0121(8), F.S., requires manufacturers to establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs.

Please provide the applicant's written policies and procedures on: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, etc.
retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; and product tracing and other requirements under the federal Drug Supply Chain Security Act (DSCSA).

Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy and procedure for recalls could be labeled or identified as "Recall Policy and Procedure" or in another manner similar to this example.

<table>
<thead>
<tr>
<th>Policies Attached?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt, security, storage, inventory, distribution/disposition of prescription drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributing oldest approved stock first (FIFO)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Identifying, recording and reporting prescription drug losses and thefts</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Maintenance, retrieval and retention of required records</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Prescription drug recalls and withdrawals</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Natural disasters and other emergencies</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Segregation and destruction of outdated prescription drugs</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Temperature and humidity monitoring</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Product Tracing and other DSCSA requirements</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

8. Will the applicant establishment purchase and subsequently direct the distribution (e.g. drop shipment) of prescription drugs on its behalf to another company, including any prescription drug active pharmaceutical ingredient (API), for which the applicant establishment is not considered the manufacturer? (For assistance in determining the definition of "distribute" see Section 499.003, Florida Statutes.) If yes, you will need additional permit(s) depending on the activity. Refer to section 499.01(2), Florida Statutes.

| Yes | No |

9. Will ANY prescription drugs, including active pharmaceutical ingredient, be stored, received, or warehoused – even temporarily – including, any customers’ return(s) or recalled prescription drugs, at the location for which the applicant is seeking a permit? If yes, then the applicant is NOT eligible for this permit. Virtual manufacturer may not possess prescription drugs.

| Yes | No |

Section VIII-- Qualify as a Manufacturer
**QUALIFYING AS A MANUFACTURER**  
(Check all that apply)

- For the purpose of the questions below, the term "affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:
  a. The business entity controls, or has the power to control, the other business entity; or
  b. Third party controls, or has the power to control, both business entities.

- FDA approvals must be in the name of the applicant as listed on this application. If the FDA approval is not in the same name as the applicant as listed on this application, you may not qualify as a manufacturer.

1. **Does the applicant hold a FDA drug application (e.g., a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a New Animal Drug Application (NADA), or an Abbreviated New Animal Drug Application (ANADA)) approved under the federal act?** If yes, provide a list of all approved applications and licenses by number on a separate sheet with the drug's respective NDC number(s) listed with FDA, and provide copies of no more than 5 FDA approval letters.
   - List of applications/licenses attached? □ Yes □ No
   - Copies of approval letters attached? □ Yes □ No

2. **Does the applicant hold a Biologics License issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262 for a drug or biologic?** If yes, provide a list of the approved licenses by number on a separate sheet, and provide a copy of no more than 5 FDA licenses for drugs or biologics.
   - List of licenses attached? □ Yes □ No
   - Copies of licenses attached? □ Yes □ No

3. **Does the applicant "manufacture" drugs or biologics that are not the subject of an approved FDA application or license?** If yes, please provide:
   a. All labeling associated with the drug or biologics manufactured and a listing of the drug's respective NDC number(s) listed with FDA by the applicant if not listed on the labeling;
   b. A written description of the applicant's intent with respect to the drug or biologic, i.e., clinical trial, distribution or commercial sale, etc.;
   c. Statement of reasoning for which the applicant claims the prescription drug can be marketed in the United States; and
   d. Documentation that the drug or biologic can be legally placed into interstate commerce as per FDA regulations, for example, a copy of section(s) of the Federal Register, Code of Federal Regulations (CFR) denoting the prescription drug Drug Efficacy Study Implementation (DESI) designation or a copy of section(s) of the CFR denoting the prescription drug remains pending final DESI review, or a copy and summary of material(s) and authoritative literature reviewed during the applicant's investigation supporting that the prescription drug has not yet been reviewed in the DESI process.
   - Labeling attached? □ Yes □ No
   - Description of intent attached? □ Yes □ No
   - Statement of reasoning attached □ Yes □ No
   - Supportive documentation attached □ Yes □ No

4. **Is the applicant a co-licensed partner of a person described in 1, 2, or 3 above, who obtains drugs or biologics directly from a person described in 1, 2, 3 above, 5 below, or another co-licensed partner of such person?** Please provide a complete, fully executed copy of no more than 5 co-licensing agreements between the applicant and the applicant's co-licensed partners.
   - Complete agreements attached? □ Yes □ No
   - Agreements are considered trade secret? □ Yes □ No
5. Is the applicant an affiliate of a person described in 1, 2, 3, or 4 above, or of another affiliate of such a person, that obtains drugs or biologics directly from a person described in 1, 2, 3 or 4 above or another affiliate of such person? If yes, please provide the following:
   a. If the applicant and the affiliate fall under the same business / organizational structure, i.e., one company is a parent, subsidiary, or sister / brother company of the other, provide written documentation describing the relationships between the companies, including, where applicable, the percentages of ownership in each company, an organizational chart with business and d/b/a names; and
   b. The name and address of the manufacturer or of the affiliate from whom the applicant obtains drugs or biologics.

   Relationship documents attached? [Yes] [No]
   Documents are considered trade secret? [Yes] [No]
   List of affiliates attached? [Yes] [No]
   List of affiliates considered trade secret? [Yes] [No]

Section IX – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: ___________________________ Date: ___________________________
Print Name: ___________________________ Title: ___________________________
Mail completed application to:
Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047
November 17, 2016

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

Re: Department of Business and Professional Regulation
   Rule 61N-2.0141, F.A.C.

Dear Ms. Holladay:

Thank you for your correspondence dated October 27, 2016 (attached). Before I endeavor to address the specifics of your correspondence, I wanted to clarify the nature of the correspondence. As you are aware, section 120.54(3)(d)1., Florida Statutes, provides in part:

"Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee."

Your correspondence does not indicate that the committee is proposing to object to the rule, thus the department is treating your comments as "written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action." If the intent of your correspondence was to notify the department of proposed committee objections, please advise as such so that we can appropriately update the department’s files. The department’s responses to the items you commented on are:

<table>
<thead>
<tr>
<th>Summary of Statement of Estimated Regulatory Costs and Legislative Ratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>The department’s determination that a statement of estimated regulatory costs was not necessary was based on the department's analysis of the impact the proposed rules in light of the statutory factors set forth in section 120.541, F.S. The department's analysis was conducted by the division and subjected to an extensive, thorough vetting process, before ultimately being approved by the agency head.</td>
</tr>
<tr>
<td>Note: Although the proposed rule establishes a new permit, for which a $1,500 biennial application fee is charged, the proposed rule does not increase any regulatory costs for entities impacted by the proposed rule. Currently, entities that engage in activities falling under this permit are required to obtain a prescription drug manufacturer permit. The fee for that permit is $1,500 biennially. The new prescription drug manufacturer - virtual permit removes some of the physical establishment requirements pertaining to storage of prescription drugs that that are placed on prescription drug manufacturers.</td>
</tr>
<tr>
<td>Summary: The department filed a Notice of Correction with respect to the summary included LICENSE EFFICIENTLY, REGULATE FAIRLY.</td>
</tr>
<tr>
<td><a href="http://WWW.MYFLORIDALICENSE.COM">WWW.MYFLORIDALICENSE.COM</a></td>
</tr>
</tbody>
</table>
with the notice of this rule; the Notice of Correction published today.

Rulemaking Authority:
The department will add section 499.05, F.S., to the rulemaking authority.

Law Implemented:
The department will add sections 499.05 and 559.79, F.S., to the law implemented.

61N-2.0111:
It appears that the reference to Rule 61N, F.A.C. instead of "Rule Title 61N, F.A.C." is technical in nature; thus the division will update this at the time of filing the rule for adoption.

DBPR-DDC-236:
Page 1:
The department is aware of Op. Att’y Gen. Fla. 75-293 (1975), but interprets this opinion in a manner slightly different from the manner. The department believes that this opinion stands for the premise that once the department has begun processing the application, the department has earned the fee and that fee is due to the department, and absent a statutory provision specifically authorizing the department to refund the fee, the department is prohibited from doing so. This is supported by the fact that numerous other professions housed within the department have statutes that specifically state which fees are refundable and which fees are nonrefundable. Usually, the statutes provide that initial application fees are nonrefundable and initial licensure fees are refundable. This makes sense as the department expends resources processing applications whether the applicant is qualified and received the license for which the applicant applied. Where the applicant is not qualified and does not receive the license, it seems that the initial licensure fees are nonrefundable. The division’s fees are not split out, thus, unless the fees fall under the provisions of section 215.08, F.S., they are nonrefundable, absent a statute to the contrary.

Pages 4, 5, and 6:
The department will be filing a Notice of Change amending the form. The form will amended to include a disclosure statement with respect to the department’s use of Social Security Numbers. The disclosure statement that will be added is:

The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a), 499.012(8)(o), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(f), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.

Section 499.012(4)(a), F.S., authorizes the division to collect “[a]ny other relevant information that the department requires.” The department believes that this authorizes the department to request the date of birth of these individuals as well as the FEID/FEIN numbers of business entities owning 10 percent or more of the outstanding stock or equity interest.
I hope that the department's responses have addressed your comments. The department will be filing the Notices of Changes as indicated above later this week. If you have any questions or concerns please give me a call at the number listed above.

Respectfully,

Reginald D. Dixon
Director

Attachment(s):
October 27, 2016 Letter
October 27, 2016

Mr. Reginald D. Dixon  
Executive Director  
Department of Business and Professional Regulation  
Division of Drugs, Devices and Cosmetics  
2601 Blairstone Road  
Tallahassee, Florida 32399-1047

Re: Department of Business and Professional Regulation  
Rule 61N-2.0141, F.A.C.

Dear Mr. Dixon:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on October 19, 2016. I have the following comments.

Summary of Statement of Estimated Regulatory Costs and Legislative Ratification:  
This proposed rule establishes a new permit, for which a $1,500 biennial application fee is charged. Please explain how the department determined that a statement of estimated regulatory costs is not required for this rule.

Summary:  
The summary of this proposed rule states, “The proposed rules adopt and incorporate the division’s permitting applications for resident and nonresident virtual prescription drug manufacturer permits and nonresident prescription drug repackagers.” It does not appear that proposed rule 61N-2.0141 pertains to virtual nonresident prescription drug manufacturer permits or to nonresident prescription drug repackager permits. Please publish a notice of correction that correctly summarizes this proposed rule.
Rulemaking Authority: It appears that section 499.05 should be cited as rulemaking authority.

Law Implemented: It appears that section 499.05 and section 559.79 should be added as laws implemented.

61N-2.0141: It appears that the reference to "Rule 61N, F.A.C." should be to "Rule Title 61N, F.A.C." See Fla. Admin. Code R. 1-1.008(1).

This rule incorporates by reference form DBPR-DDC-235, Application for Permit as a Prescription Drug Manufacturer – Virtual, effective July 2016.

DBPR-DDC-235:
Page 1: Please explain why the form states that the $1,500 biennial application fee is nonrefundable. Absent statutory authority to the contrary, it appears that if an applicant requests a refund of this fee prior to any action being taken concerning the applicant’s qualifications, the fee should be refundable. See Op. Att’y Gen. Fla. 75-293 (1975). It does not appear that section 499.041(1)(a), which authorizes this fee, states that the application fee is nonrefundable.

Pages 4, 5, and 6: These pages request the social security numbers and dates of birth of each owner, partner, member, manager, officer, director, chief executive or other person who directly controls the operation of the business entity, as well as of the social security numbers and dates of birth of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. The form also requests the FEID/FEIN if the person owning 10 percent or more of the outstanding stock or equity interest is a business entity. It appears the request for these social security numbers is asked pursuant to section 559.79(1).

Please include a written statement on the form that complies with section 119.0715(a)2., which requires each agency to state in writing the purpose for the collection of an individual’s social security number. Also, although not a matter within the purview of this committee, you should be aware that the Federal Privacy Act of 1974, Dec. 31, 1974, Pub. L. No. 93-579, section 7, 88 Stat. 1896, 1909, codified at 5 U.S.C. section 552a, also governs the disclosure of social security numbers.

Please explain which statute cited as a law implemented authorizes the department to request the date of birth of these individuals.
Mr. Reginald D. Dixon
October 27, 2016
Page 3

Please explain which statute cited as a law implemented authorizes the department to request the FEID/FEIN of the business entities owning 10 percent or more of the outstanding stock or equity interest.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Ms. Renee Alsobrook
Chief of Compliance and Enforcement

MCH:SA WORD/MARJORIE/6IN_2.0141LS102716_161809
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Prescription Drug Manufacturer - Virtual</td>
<td>✗ Fee of $1,650, which includes a $1,500 nonrefundable biennial application fee and $150.00 initial inspection fee. If the applicant is applying for multiple manufacturing permits in the applicant’s name and at the applicant’s address, the applicant is only required to pay for the permit that has the highest fee.</td>
</tr>
<tr>
<td></td>
<td>✗ Make cashier’s check, corporate check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>✗ If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>✗ Sign and date the Affidavit section of the application.</td>
</tr>
<tr>
<td></td>
<td>Mail completed application to: Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047</td>
</tr>
</tbody>
</table>

PLEASE NOTE:

PLEASE NOTE:

- Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.

- The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a)(f, 499.012(8)(o), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.
Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3345/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3345/1020]

Current Permit Number: 

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN: 

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name: 

FICTITIOUS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations). This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: 

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: 

________________________________________
## APPLICANT MAILING ADDRESS

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>County:</th>
<th>Phone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

## PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED

(only if different from mailing address) Check [ ] if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>County:</th>
<th>Phone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

## Email Address:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>

## APPLICATION CONTACT

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>E-Mail Address:</th>
<th></th>
</tr>
</thead>
</table>

## EMERGENCY CONTACT INFORMATION

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Position/Title:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Street Address:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Phone Number:</th>
<th>E-Mail Address:</th>
</tr>
</thead>
</table>
**OPERATING HOURS**

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to a.m./p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td></td>
</tr>
<tr>
<td>Tue</td>
<td></td>
</tr>
<tr>
<td>Wed</td>
<td></td>
</tr>
<tr>
<td>Thu</td>
<td></td>
</tr>
<tr>
<td>Fri</td>
<td></td>
</tr>
<tr>
<td>Sat</td>
<td></td>
</tr>
<tr>
<td>Sun</td>
<td></td>
</tr>
</tbody>
</table>

**Section III – Ownership Information**

**TYPE OF OWNERSHIP**

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other: _____________________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

State: ____________________

List name and address of the applicant’s registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations’ webpage, that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

Name: ____________________

Address: ____________________

City: ____________________  State: ____________________  Zip Code (+4 Optional): ____________________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1. Name & Title: ____________________  Social Security #: ____________________  Date of Birth: ____________________  % of Ownership: ____________________

   Street Address: ____________________  City: ____________________

2. Name & Title: ____________________  Social Security #: ____________________  Date of Birth: ____________________  % of Ownership: ____________________
<table>
<thead>
<tr>
<th>Street Address:</th>
<th>City:</th>
<th>State:</th>
<th>Zip Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>4. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>5. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>6. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>7. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>8. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. If such person is a business entity, list the business entity name, FEID/FEIN and percentage of ownership and check the box labeled "N/A" for date of birth.

<table>
<thead>
<tr>
<th>Name:</th>
<th>SSN/FEID/FEIN#</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>2. Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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<td></td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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<td>3</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<tr>
<td></td>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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<tr>
<td>4</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<td></td>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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<tr>
<td>5</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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<td>6</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<td>Street Address:</td>
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<td>State:</td>
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<td>7</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
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<td></td>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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<td>8</td>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth: □ N/A</td>
</tr>
<tr>
<td></td>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box □ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary.) □ Yes □ No

Parent Company Name                  % of Ownership

Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box □ and write "N/A" in the lines below.)
Is diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care services provided at the address of the establishment that is the subject of this permit application? If so, please list the name of the company/companies providing such services below and provide the corresponding license or permit number(s) issued by the State of Florida and/or federal government. (Use additional sheet(s) if necessary).

Name:  
Permit/License No.:  
Issuing Agency:  

Section IV – Background Questions

**BACKGROUND QUESTIONS**

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

If you answer “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

1. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any “affiliated party” (defined above) been found guilty of (regardless of adjudication), or pled no contest to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?

2. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any affiliated party (defined above) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?

3. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any affiliated party (defined above) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?

4. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any affiliated party (defined above) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?

5. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any affiliated party (defined above) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?

6. **Yes**  
   If yes, explain in detail in Section V  
   **No**  
   Has the applicant or any affiliated party (defined above) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address).
### Section V - Explanation(s) for “Yes” response(s) to background question(s)

**EXPLANATION**

<table>
<thead>
<tr>
<th>Explanation</th>
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### Section VI - Other Permits or Licenses

#### PERMITS OR LICENSES

1. Are there any permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If yes, please provide a list of all such permits including the issuing agency, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no permits or licenses.)

   - Yes
   - No
   - Permit/license list provided.
   - No permits/licenses.

2. Is the applicant licensed in any other state as a manufacturer, repackager, distributor or wholesaler of prescription drugs? (If yes, please provide a list all such permits including the state, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no other permits or licenses.)

   - Yes
   - No
   - Permit/license list provided.
   - No permits/licenses.

3. Does or will the applicant establishment sell prescription drugs in or from Florida? (If no, provide the name and address from which the drugs are sold in or from Florida in the spaces provided below. Use additional sheets if needed.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Physical Address</th>
<th>Florida Permit/License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

DBPR-DDC-235 - Application for Permit as a Prescription Drug Manufacturer – Virtual
Incorporated by rules: 61N-2.0141, F.A.C.
Eff. Date: July 2016
Page 9 of 15
4. Provide information on the establishment(s) that will ship or physically transfer prescription drugs for which the applicant is considered the manufacturer into, in or from Florida on the applicant establishment's behalf.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Florida Permit Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Section VII – Prescription Drug Manufacturing Activity

**MANUFACTURING ACTIVITIES**

Generally identify the applicant's intended customers, the persons and entities that will purchase prescription drugs from the applicant establishment after permit issuance.

- Manufacturers
- Hospitals
- Veterinarians
- Other (explain)
- Wholesalers
- Practitioners
- Pharmacies
- Health Care Clinics

Identify the types of prescription drugs that will be distributed by this virtual manufacturer establishment for which this establishment is considered the manufacturer.

- Human Prescription Drugs
- Veterinary Prescription Drugs
- Solid Dose
- Repackage – From Bulk as the manufacturer, not as a repackager
- Liquids (Oral)
- Repackage – From Stock as the manufacturer, not as a repackager
- Injectables
- Ophthalmic
- Topical
- Compressed Medical Gases
- Dental
- Refrigerated (Human, Veterinary, API or Otherwise)
- Other (explain)
- Frozen (Human, Veterinary, API or Otherwise)

- Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):
  - Manufacturers
  - Pharmacies for Compounding
  - Other explain

Controlled Substances: Provide your DEA Number: __________________ or check ☐ No DEA Number

Check Schedules: ☐ Sch II ☐ Sch III ☐ Sch IV ☐ Sch V

Identify type of operation:

- FDA Drug Application Holder
  - (e.g. NDA, ANDA, BLA, NADA, ANADA holder)
- Co-licensed partner of the FDA Drug Application Holder
- Own Label Manufacturer

Provide your Federal Food and Drug Administration (FDA) drug establishment registration number.

- FDA Establishment Registration Number: __________________

or

- No FDA Establishment Number AND a written explanation is attached ☐

1. Are prescription drugs to be distributed under this permit intended for export? (Note: A permit may be required for recipients that are freight forwarders handling)

☐ Yes ☐ No
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Do you manufacture a prescription drug as a finished product? (If no, explain on a separate sheet providing accurate details and provide an example of a typical label.)</td>
<td></td>
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<tr>
<td>3. Are you submitting a product registration application and labels for your prescription drugs with this application?</td>
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<tr>
<td>Are the applicant's drugs manufactured outside of Florida?</td>
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<tr>
<td>If the applicant's prescription drugs are manufactured in Florida, but the applicant is not submitting a product registration application and labels with this application please provide a written explanation.</td>
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<tr>
<td>Written explanation attached?</td>
<td></td>
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<tr>
<td>Note: If you manufacture a prescription drug in Florida, you <strong>CANNOT SELL</strong> that drug until that drug has been registered with the department. Selling a prescription drug before it is registered with the division is the basis for application permit denial and enforcement action by the division.</td>
<td></td>
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</tr>
<tr>
<td>4. Does the applicant establishment intend to distribute prescription drug samples in the State of Florida through its agents, employees, or independent contractors? (If yes, a Complimentary Drug Distributor permit is required. Please review sections 499.01 and 499.028, Florida Statutes.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Will all required records be stored and maintained at applicant's physical address? (If no, provide the name and address of the establishment(s) where all required records will be stored and maintained under question #5a.)</td>
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</tr>
<tr>
<td>5a. Name and physical address where required records will be stored:</td>
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<td></td>
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<tr>
<td>Name:</td>
<td></td>
<td></td>
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<tr>
<td>Street Address:</td>
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<td>City:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zip Code (+4 optional):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Will the required records be computerized, automated or stored electronically?</td>
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<tr>
<td>If yes, will you have a back-up procedure to be able to provide required records?</td>
<td></td>
<td></td>
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<tr>
<td>If electronically stored and not maintained as a scanned image, is the electronic data (used to generate reprints or the required document) maintained unchanged from the time of the actual distribution or activity?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Section 499.0121(2), F.S., requires establishments to be equipped with a) an alarm system to detect entry after hours and b) a security system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. Please provide a written description of the alarm and security systems that includes both the type of systems used and how the systems are monitored.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm system description included?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Security system description included?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Sections 499.0121(a) and 499.0121(8), F.S., requires manufacturers to establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Please provide the applicant's written policies and procedures on: the receipt, security, storage,
inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; and product tracing and other requirements under the federal Drug Supply Chain Security Act (DSCSA).

Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy and procedure. For example, the policy and procedure for recalls could be labeled or identified as "Recall Policy and/or Procedure" or in another manner similar to this example.

<table>
<thead>
<tr>
<th>Policy Attached?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt, security, storage, inventory, distribution/disposition of prescription drugs</td>
</tr>
<tr>
<td>Distributing oldest approved stock first (FIFO)</td>
</tr>
<tr>
<td>Identifying, recording and reporting prescription drug losses and thefts</td>
</tr>
<tr>
<td>Maintenance, retrieval and retention of required records</td>
</tr>
<tr>
<td>Prescription drug recalls and withdrawals</td>
</tr>
<tr>
<td>Natural disasters and other emergencies</td>
</tr>
<tr>
<td>Segregation and destruction of outdated prescription drugs</td>
</tr>
<tr>
<td>Temperature and humidity monitoring</td>
</tr>
<tr>
<td>Product tracing and other DSCSA requirements</td>
</tr>
</tbody>
</table>

9. Will you distribute prescription drugs, including any active pharmaceutical ingredient (API), used or intended for use in the manufacture of a prescription drug from the establishment? (For assistance in determining the definition of "distribute" see Section 499.003, Florida Statutes.)

| Yes | No |

10. Will ANY prescription drugs, including active pharmaceutical ingredient, be stored, received, or warehoused – even temporarily – including customer’s return(s) or recalled prescription drugs at the location for which the applicant is seeking a permit? If yes, then the applicant is NOT eligible for this permit. Virtual manufacturers may not possess prescription drugs.

| Yes | No |

11. Provide the date the establishment will be ready and available for inspection. This is the earliest date the applicant may be deemed complete.

__/__/20__

Section VIII - Qualify as a Manufacturer
### QUALIFYING AS A MANUFACTURER

(Check all that apply)

- For the purpose of the questions below, the term "affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:
  a. The business entity controls, or has the power to control, the other business entity; or
  b. Third party controls, or has the power to control, both business entities.

- FDA approvals must be in the name of the applicant as listed on this application. If the FDA approval is not in the same name as the applicant as listed on this application, you may not qualify as a manufacturer.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the applicant hold a FDA drug application (e.g., a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a New Animal Drug Application (NADA), or an Abbreviated New Animal Drug Application (ANADA)) approved under the federal act? If yes, provide a list of all approved applications and licenses by number on a separate sheet with the drug's respective NDC number(s) listed with FDA, and provide copies of no more than 5 FDA approval letters. List of applications/licenses attached?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Copies of approval letters attached?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2. Does the applicant hold a Biologics License issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262 for a drug or biologic? If yes, provide a list of the approved licenses by number on a separate sheet, and provide a copy of no more than 5 FDA licenses for drugs or biologics. List of licenses attached?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Copies of licenses attached?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
| 3. Does the applicant “manufacture” drugs or biologics that are not the subject of an approved FDA application or license? If yes, please provide:
  a. All labeling associated with the drug or biologics manufactured and a listing of the drug’s respective NDC number(s) listed with FDA by the applicant if not listed on the labeling;
  b. A written description of the applicant’s intent with respect to the drug or biologic, i.e., clinical trial, distribution or commercial sale, etc.;
  c. Statement of reasoning for which the applicant claims the prescription drug can be marketed in the United States; and
  d. Documentation that the drug or biologic can be legally placed into interstate commerce as per FDA regulations, for example, a copy of section(s) of the Federal Register, Code of Federal Regulations (CFR) denoting the product Drug Efficacy Study Implementation (DESI) designation or a copy of section(s) of the CFR denoting the prescription drug remains pending final DESI review, or a copy and summary of material(s) and authoritative literature reviewed during the applicant’s investigation supporting that the prescription drug has not yet been reviewed in the DESI process. Labeling attached? | Yes | No |
| Description of intent attached?                                         | Yes | No |
| Statement of reasoning attached                                         | Yes | No |
| Supportive documentation attached?                                      | Yes | No |
| 4. Is the applicant a co-licensed partner of a person described in 1, 2, or 3 above, who obtains drugs or biologics directly from a person described in 1, 2, 3 above, 5 below, or another co-licensed partner of such person? Please provide a complete, fully executed copy of no more than 5 co-licensing agreements between the applicant and the applicant’s co-licensed partners. Complete agreements attached? | Yes | No |
| Agreements are considered trade secret?                                  | Yes | No |
5. Is the applicant an affiliate of a person described in 1, 2, 3, or 4 above, or of another affiliate of such a person, that obtains drugs or biologics directly from a person described in 1, 2, 3 or 4 above or another affiliate of such person? If yes, please provide the following:

a. If the applicant and the affiliate fall under the same business / organizational structure, i.e., one company is a parent, subsidiary, or sister/brother company of the other, provide written documentation describing the relationships between the companies, including, where applicable, the percentages of ownership in each company, an organizational chart with business and d/b/a names; and

b. The name and address of the manufacturer or of the affiliate from whom the applicant obtains drugs or biologics.

Relationship documents attached? □ Yes □ No
Documents are considered trade secret? □ Yes □ No
List of affiliates attached? □ Yes □ No
List of affiliates considered trade secret? □ Yes □ No

Section IX – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: ________________________________ Date: ________________________________

Print Name: ________________________________ Title: ________________________________
Mail completed application to:
Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047
November 17, 2016

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

Re: Department of Business and Professional Regulation
Rule 61N-2.0151, F.A.C.

Dear Ms. Holladay:

Thank you for your correspondence dated October 27, 2016 (attached). Before I endeavor to address the specifics of your correspondence, I wanted to clarify the nature of the correspondence. As you are aware, section 120.54(3)(d)1., Florida Statutes, provides in part:

"Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee."

Your correspondence does not indicate that the committee is proposing to object to the rule, thus the department is treating your comments as "written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action." If the intent of your correspondence was to notify the department of proposed committee objections, please advise as such so that we can appropriately update the department’s files. The department’s responses to the items you commented on are:

Summary of Statement of Estimated Regulatory Costs and Legislative Ratification

The department’s determination that a statement of estimated regulatory costs was not necessary was based on the department’s analysis of the impact the proposed rules in light of the statutory factors set forth in section 120.541, F.S. The department’s analysis was conducted by the division and subjected to an extensive, thorough vetting process, before ultimately being approved by the agency head.

Note: Although the proposed rule establishes a new permit, for which a $1,500 biennial application fee is charged, the proposed rule does not increase any regulatory costs for entities impacted by the proposed rule. Currently, entities that engage in activities falling under this permit are required to obtain an out-of-state prescription drug wholesale distributor permit. The fee for that permit is $800 annually; biennially permits are not currently available. Additionally, out-of-state prescription drug wholesale distributors must carry a bond ($100,000) and employ a certified designated representative (CDR) that is permitted by the division after taking and passing an examination. The new nonresident prescription drug repackager permit removes the requirements for the bond and the CDR and

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WWW.MYFLORIDALICENSE.COM
provides for biennial permitting.

Summary: The department filed a Notice of Correction with respect to the summary included with the notice of this rule; the Notice of Correction published today.

Rulemaking Authority: The department will add section 499.05, F.S., to the rulemaking authority.

Law Implemented: The department will add sections 499.05 and 559.79, F.S., to the law implemented.

61N-2.0111: It appears that the reference to Rule 61N, F.A.C. instead of "Rule Title 61N, F.A.C." is technical in nature; thus the division will update this at the time of filing the rule for adoption.

DBPR-DDC-236:
Page 1: The department is aware of Op. Att’y Gen. Fla. 75-293 (1975), but interprets this opinion in a manner slightly different from the manner. The department believes that this opinion stands for the premise that once the department has begun processing the application, the department has earned the fee and that fee is due to the department, and absent a statutory provision specifically authorizing the department to refund the fee, the department is prohibited from doing so. This is supported by the fact that numerous other professions housed within the department have statutes that specifically state which fees are refundable and which fees are nonrefundable. Usually, the statutes provide that initial application fees are nonrefundable and initial licensure fees are refundable. This makes sense as the department expends resources processing applications whether the applicant is qualified and received the license for which the applicant applied. Where the applicant is not qualified and does not receive the license, it seems that the initial licensure fees are nonrefundable. The division’s fees are not split out, thus, unless the fees fall under the provisions of section 215.08, F.S., they are nonrefundable, absent a statute to the contrary.

Pages 4, 5, and 6: The department will be filing a Notice of Change amending the form. The form will amended to include a disclosure statement with respect to the department’s use of Social Security Numbers. The disclosure statement that will be added is:

The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a)(f), 499.012(8)(o), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.

Section 499.012(4)(a)(f), F.S., authorizes the division to collect “[a]ny other relevant information that the department requires.” The department believes that this authorizes the department to request the date of birth of these individuals as
well as the FEID/FEIN numbers of business entities owning 10 percent or more of the outstanding stock or equity interest.

Page 12, Section VIII: The department will be filing a Notice of Change removing the phrase “If signed by someone other than an owner or officer, you must submit a letter from an owner or officer authorizing the signer to bind the applicant” from the application form.

I hope that the department’s responses have addressed your comments. The department will be filing the Notices of Changes as indicated above later this week. If you have any questions or concerns please give me a call at the number listed above.

Respectfully,

Reginald D. Dixon
Director

Attachment(s):
October 27, 2016 Letter
October 27, 2016

Mr. Reginald D. Dixon  
Executive Director  
Department of Business and Professional Regulation  
Division of Drugs, Devices and Cosmetics  
2601 Blairstone Road  
Tallahassee, Florida 32399-1047

Re: Department of Business and Professional Regulation  
Rule 61N-2.0151, F.A.C.

Dear Mr. Dixon:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on October 20, 2016. I have the following comments.

Summary of Statement of Estimated Regulatory Costs and Legislative Ratification:  
This proposed rule establishes a new permit, for which a $1,500 biennial application fee is charged. Please explain how the department determined that a statement of estimated regulatory costs is not required for this rule.

Summary: The summary of this proposed rule states, "The proposed rules adopt and incorporate the division’s permitting applications for resident and nonresident virtual prescription drug manufacturer permits and nonresident prescription drug repackagers." It does not appear that proposed rule 61N-2.0151 pertains to virtual prescription drug manufacturer permits or to virtual nonresident prescription drug manufacturer permits. Please publish a notice of correction that correctly summarizes this proposed rule.

Rulemaking Authority: It appears that section 499.05 should be cited as rulemaking authority.
Mr. Reginald D. Dixon
October 27, 2016
Page 2

Law Implemented: It appears that section 499.05 and section 559.79 should be added as laws implemented.


This rule incorporates by reference form DBPR-DDC-237, Application for Permit as a Prescription Drug Repackager, effective July 2016. Please correct the title of this form in the rule text. The form provided for review is entitled “Application for Permit as a Nonresident Prescription Drug Repackager.”

DBPR-DDC-237:
Page 1: Please explain why the form states that the $1,500 biennial application fee is nonrefundable. Absent statutory authority to the contrary, it appears that if an applicant requests a refund of this fee prior to any action being taken concerning the applicant’s qualifications, the fee should be refundable. See Op. Att’y Gen. Fla. 75-293 (1975). It does not appear that section 499.041(1)(a), which authorizes this fee, states that the application fee is nonrefundable.

Pages 4, 5, and 6: These pages request the social security numbers and dates of birth of each owner, partner, member, manager, officer, director, chief executive or other person who directly controls the operation of the business entity, as well as of the social security numbers and dates of birth of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. The form also requests the FEID/FEIN if the person owning 10 percent or more of the outstanding stock or equity interest is a business entity. It appears the request for these social security numbers is asked pursuant to section 559.79(1).

Please include a written statement on the form that complies with section 119.071(5)(a)2., which requires each agency to state in writing the purpose for the collection of an individual’s social security number. Also, although not a matter within the purview of this committee, you should be aware that the Federal Privacy Act of 1974, Dec. 31, 1974, Pub. L. No. 93-579, section 7, 88 Stat. 1896, 1909, codified at 5 U.S.C. section 552a, also governs the disclosure of social security numbers.

Please explain which statute cited as a law implemented authorizes the department to request the date of birth of these individuals.
Mr. Reginald D. Dixon  
October 27, 2016  
Page 3

Please explain which statute cited as a law implemented authorizes the department to request the FEID/FEIN of the business entities owning 10 percent or more of the outstanding stock or equity interest.

Page 12, Section VIII: This section states that the owner or officer must sign the application, but then states, "If signed by someone other than an owner or officer, you must submit a letter from an owner or officer authorizing the signer to bind the applicant."

Section 559.79(2) states, "Each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant, without the need for witnesses unless otherwise required by law." Thus, it appears that only the applicant, owner, or the chief executive are statutorily authorized to sign the application. Please explain the department’s authority to allow a person other than one of these individuals to sign the application form. Also, please explain the department’s authority to allow an owner or an officer to delegate that responsibility to another person. See § 120.52(8)(c), Fla. Stat.

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. Renee Alsobrook  
Chief of Compliance and Enforcement

MCH:SA WORD/MARJORIE/61N_2.0151LS102716_151831
**APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.**

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Nonresident Prescription Drug Repackager</td>
<td>☐ Enclose the $1,500.00 nonrefundable biennial application fee. If the applicant is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit that has the highest fee.</td>
</tr>
<tr>
<td></td>
<td>☐ Make cashier's check, corporate check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>☐ If you answered &quot;Yes&quot; to any question in Section IV, enclose a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>☐ Sign and date the Affidavit section of the application.</td>
</tr>
</tbody>
</table>

Submit the completed application with enclosures to:
Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399-1047

**PLEASE NOTE:**

- Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.

- The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a), 499.012(8)(c), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by § 559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics  

Application for Permit as a Nonresident Prescription Drug Repackager  
Form No.: DBPR-DDC-237  

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I - Application Type

<table>
<thead>
<tr>
<th>CHECK ONE OF THE APPLICATION TYPES</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ New Application [3347/1020]</td>
</tr>
<tr>
<td>☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3347/1020]</td>
</tr>
<tr>
<td>Permit Number under previous ownership: ________________________________</td>
</tr>
</tbody>
</table>

Section II - Applicant Information

<table>
<thead>
<tr>
<th>APPLICANT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER</td>
</tr>
<tr>
<td>This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).</td>
</tr>
<tr>
<td>Applicant's TIN/FEIN: ________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FULL LEGAL NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>The &quot;full legal name&quot; is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation's full legal name would normally be the name that is found in the corporation's articles of incorporation.</td>
</tr>
<tr>
<td>Applicant's Full Legal Name: ________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FICTITIOUS, TRADE, OR BUSINESS NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the applicant intends to operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations). This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.</td>
</tr>
<tr>
<td>☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above.</td>
</tr>
<tr>
<td>☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: ________________________________</td>
</tr>
<tr>
<td>The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: ________________________________</td>
</tr>
</tbody>
</table>
**APPLICANT MAILING ADDRESS**

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Email Address:</th>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

**PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED**

(only if different from mailing address) Check ✔ if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Email Address:</th>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

**APPLICATION CONTACT**

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Email Address:</th>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

**EMERGENCY CONTACT INFORMATION**

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Position/Title:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Street Address:</th>
<th></th>
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</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Email Address:</th>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>
OPERATING HOURS

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>Start Time</th>
<th>End Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Tue</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Wed</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Thu</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Fri</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Sat</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
<tr>
<td>Sun</td>
<td>8:00 a.m.</td>
<td>5:00 p.m.</td>
</tr>
</tbody>
</table>

Section III – Ownership Information

TYPE OF OWNERSHIP

☐ Publicly Held Corporation  ☐ Closely Held Corporation  ☐ Limited Liability Company

☐ Charitable Organization—501(c)(3)  ☐ Sole Proprietorship  ☐ Government

☐ Partnership – General  ☐ Professional Corporation or Association  ☐ Professional Limited Liability Company

☐ Partnership – Other, Including Limited Liability Partnership and Limited Partnership

☐ Other: __________________________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

☐ N/A (Partnership – General or Sole Proprietorship)

State: _______________________

List name and address of the applicant’s registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.

☐ N/A (Partnership – General or Sole Proprietorship)

Name: __________________________

Address: __________________________

City: __________________ State: __________________ Zip Code (+4 optional): __________________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1. Name & Title: __________________ Social Security #: __________________ Date of Birth: ___________ % of Ownership: ___________

   Street Address: __________________ City: __________________ State: __________________ Zip Code: __________________

2. Name & Title: __________________ Social Security #: __________________ Date of Birth: ___________ % of Ownership: ___________
<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Name &amp; Title:</td>
<td>Social Security #:</td>
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</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>
List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity. If such person is a business entity, list the business entity name, FEID/FEIN and percentage of ownership and check the box labeled “N/A” for date of birth.

<table>
<thead>
<tr>
<th>Name:</th>
<th>SSN/FEID/FEIN#</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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<tr>
<td>Name:</td>
<td>SSN/FEID/FEIN#</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>
List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box □ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant’s name and address. (If no, please check this box □ and write “N/A” in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Is diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care services provided at the address of the establishment that is the subject of this permit application? If so, please list the name of the company/companies providing such services below and provide the corresponding license or permit number(s) issued by your residing state’s regulatory authority. (Use additional sheet(s) if necessary).

<table>
<thead>
<tr>
<th>Name:</th>
<th>Permit/License No.:</th>
<th>Issuing Agency:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section IV – Background Questions

**BACKGROUND QUESTIONS**

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

If you answer “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

<table>
<thead>
<tr>
<th>1. Has the applicant or any “affiliated party” (defined above) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Has the applicant or any affiliated party (defined above) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
</tbody>
</table>
3.  □ Yes  If yes, explain in detail in Section V  □ No  Has the applicant or any affiliated party (defined above) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?

4.  □ Yes  If yes, explain in detail in Section V  □ No  Has the applicant or any affiliated party (defined above) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?

5.  □ Yes  If yes, explain in detail in Section V  □ No  Has the applicant or any affiliated party (defined above) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?

6.  □ Yes  If yes, explain in detail in Section V  □ No  Has the applicant or any affiliated party (defined above) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address).

Section V – Explanation(s) for “Yes” response(s) to background question(s)

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<th>EXPLANATION</th>
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Section VI – Other Permits or Licenses

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<th>PERMITS OR LICENSES</th>
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<tr>
<td>1. Are there any permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If yes, please provide a list of all such permits including the issuing agency, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no other permits or licenses.).</td>
</tr>
<tr>
<td>□ Yes  □ No</td>
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<tr>
<td>□ Permit/licensure list provided.</td>
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<td>□ No permits/licenses.</td>
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2. Is the applicant licensed or permitted to repackage prescription drugs at the location of the establishment by the licensing or permitting authority in the state where the establishment is located? □ Yes □ No
   - Yes – Resident license attached.
   - No – Not permitted in resident state.
   - No – Not permitted and not required to be permitted in resident state; written explanation attached with a copy of relevant regulation and/or laws showing that no permit is required.

3. Is the applicant licensed in any other state as a manufacturer, repackager, distributor or wholesaler of prescription drugs? (If yes, please provide a list all such permits including the state, the permit/license type, the permit/license number and the expiration date. If not, check the box indicating no other permits or licenses.). □ Yes □ No
   - Permit/license list provided.
   - No permits/licenses.

4. Does or will the applicant establishment sell prescription drugs into Florida? (If no, provide the name and address from which the drugs are sold into Florida in the spaces provided below. Use additional sheets if needed.) □ Yes □ No

4a. 
<table>
<thead>
<tr>
<th>Name</th>
<th>Physical Address</th>
<th>Florida Permit/License Number</th>
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5. Does or will the applicant establishment ship or otherwise physically transfer prescription drugs in or into Florida? (If no, provide name, address, and Florida permit number of the shipper/transferor below). □ Yes □ No

5a. 
<table>
<thead>
<tr>
<th>Shipper’s Name</th>
<th>Shipper’s Address</th>
<th>Shipper’s Florida Permit Number</th>
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**Section VII – Prescription Drug Repackaging Activity**

**REPACKAGING ACTIVITIES**

Generally identify the applicant’s intended customers, the persons and entities that will purchase or receive repackaged prescription drugs from the applicant after permit issuance.

- [ ] Manufacturers
- [ ] Wholesalers
- [ ] Pharmacies
- [ ] Hospitals
- [ ] Practitioners
- [ ] Health Care Clinics
- [ ] Veterinarians
- [ ] Other (explain) ________________________________
Identify the types of prescription drugs the applicant will repackage or distribute under this permit. Check all that apply.

- [ ] Human Prescription Drugs
  - [ ] Solid Dose
  - [ ] Liquids (Oral)
  - [ ] Injectables
  - [ ] Topical
  - [ ] Dental
  - [ ] Ophthalmic
  - [ ] Compressed Medical Gases

- [ ] Veterinary Prescription Drugs
  - [ ] Repackage – From Bulk
  - [ ] Repackage – From Stock
  - [ ] Refrigerated (Human, Veterinary, API or Otherwise)
  - [ ] Frozen (Human, Veterinary, API or Otherwise)

Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):
- [ ] Manufacturers
- [ ] Pharmacies for Compounding
- [ ] Other explain __________

Controlled Substances: Provide your DEA Number: ____________ or check [ ] No DEA Number

Check Schedules: [ ] Sch II [ ] Sch III [ ] Sch IV [ ] Sch V

Identify type of operation.

- [ ] Contract Repackager – does not take title to drugs that are repackaged.
- [ ] Own Label Repackager - takes title to drugs that are repackaged.

Provide your Federal Food and Drug Administration (FDA) drug establishment registration number.

- [ ] FDA drug Establishment Registration Number: ____________
  or [ ] No FDA Establishment Number AND a written explanation is attached [ ]

1. Are prescription drugs to be distributed under this permit intended for export? (Note: A permit may be required for Florida recipients that are freight forwarders handling prescription drugs in Florida.)
   - [ ] Yes [ ] No

2. Will all required records be stored and maintained at applicant’s physical address? (If no, provide the name and address of the establishments where all required records will be stored and maintained under question #2a.) Please use additional sheets if necessary.
   - [ ] Yes [ ] No

2a. Name and physical address where required records are stored

   Establishment name:

   Street Address:

   City: State: Zip Code (+4 optional):

3. Will the required records be computerized, automated or stored electronically?
   - [ ] Yes [ ] No
     If yes, will you have a back-up procedure to be able to provide required records?
     - [ ] Yes [ ] No
     If electronically stored and maintained as a scanned image, is the electronic data maintained unchanged from the time of creation, receipt, purchase or distribution, depending on the document type?
     - [ ] Yes [ ] No

4. Is there a quarantine area at the applicant’s establishment? (If no, complete below and provide a written explanation on a separate sheet.)
   - [ ] Yes [ ] No
   Explanation included? [ ] Yes [ ] No
5. Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's repackaged and distributed prescription drugs) to ensure safe storage? □ Yes □ No

Does the applicant establishment have adequate temperature and humidity monitoring recording devices or logs to document proper storage of prescription drugs? □ Yes □ No

6. Section 499.012(2), F.S., requires establishments to be equipped with a) an alarm system to detect entry after hours and b) a security system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. Please provide a written description of the alarm and security systems that includes both the type of systems used and how the systems are monitored.

Alarm system description included? □ Yes □ No

Security system description included? □ Yes □ No

7. Sections 499.01(2)(a)1. and 499.0121(8), F.S., requires repackers to establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs.

Please provide the applicant's written policies and procedures on: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction documentation of outdated prescription drugs; temperature and humidity monitoring; and product tracing and other requirements under the federal Drug Supply Chain Security Act (DSCSA) or 21 USC 360eee-1.

Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy and procedure for recalls could be labeled or identified as "Recall Policy and Procedure" or in another manner similar to this example.

Policy Attached?

- Receipt, security, storage, inventory, distribution/disposition of prescription drugs □ Yes □ No
- Distributing oldest approved stock first (FIFO) □ Yes □ No
- Identifying, recording and reporting prescription drug losses and thefts □ Yes □ No
- Maintenance, retrieval and retention of required records □ Yes □ No
- Prescription drug recalls and withdrawals □ Yes □ No
- Natural disasters and other emergencies □ Yes □ No
- Segregation and destruction of outdated prescription drugs □ Yes □ No
- Temperature and humidity monitoring □ Yes □ No
- Product tracing and other DSCSA requirements □ Yes □ No

8. Do you intend to distribute prescription drug samples directly or through your agents, employees, or independent contractors into Florida? (If yes, a Complimentary Drug Distributor permit is required.) □ Yes □ No

9. Does the applicant establishment intend to sell or distribute into Florida prescription drugs that the establishment does not repackage? (If yes, you will need an Out-of-State Prescription Drug Wholesale Distributor permit or other applicable permit under section 499.01, F.S. depending on your activities.) □ Yes □ No
Section VIII – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Owner or Officer: __________________________ Date: ____________

Print Name: __________________________ Title: __________________________

Mail completed application to:

Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

AUGUST 18, 2016

Reported by:

CLARA C. ROTRUCK
Court Reporter
TELEPHONIC PROCEEDINGS

CHAIRMAN CACCIATORE: Good morning everyone.

This is Gary Cacciatore. I would like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

I would like to start with a roll call. Do we have a court reporter on the line?

THE COURT REPORTER: Yes, I am on the line.

CHAIRMAN CACCIATORE: Thank you very much. I just want to remind everyone we do have a court reporter. Rather than taking Minutes for the meeting we will just have a transcript prepared by the court reporter. So please identify yourself before you speak so the court reporter will know who is speaking on the call.

And those that are on the line, if you can put yourselves on mute that will help unless you would like to speak and obviously come off of that.

So let's start with a roll call. Ms. Greene.

MS. GREENE: Mike Ayotte.

MR. AYOTTE: Here.

MS. GREENE: Steve Mays.

MR. MAYS: Here.

MS. GREENE: Scott Brock.

MR. BROCK: Here.
MS. GREENE: Arlene Elliott.

MS. ELLIOTT: Here.

MS. GREENE: Dean Ellis.

MR. ELLIS: Here.

MS. GREENE: Bill Mahoney.

MR. MAHONEY: Here.

MS. GREENE: Patrick Barnes.

MR. BARNES: Patrick Barnes here, yes.

MS. GREENE: Jeenu Phillips.

MR. PHILLIPS: Here.

MS. GREENE: Peter Hart.

MR. HART: Here.

MS. GREENE: Gary Cacciatore.

CHAIRMAN CACCIATORE: Here. Thank you everyone for your participation.

So a couple of things just to start out. Tab one we have got the Chair's report. You will notice there is not a lot of stuff on the agenda this time.

So first of all let me thank everyone for showing up at a meeting where we don't have a lot to discuss. So I really appreciate that. This is my last meeting as you guys know. So I am sure that is why everybody showed up.

But I just wanted to say a few words about
that. There is not a lot of stuff on the agenda and I think that reflects upon two things. It reflects upon where we are as a council and where the Division is and the Department is. We have come a long, long way. This council was put together, I think it was 12 years ago or so, yes, 10 years, 11 years ago.

And at the time when the council was put together there were a lot of issues, there was a lot of problems. There was not a lot of cooperation I think between industry and the Department, and the agenda was full. So this council was put together to address a lot of those issues.

And more importantly to protect the public health and there were problems with that at that time as well. And as Florida started to address that very aggressively it formed fruit and we have a very well run council now, a very well run Division and Department.

And so as I have been on here for eight years what I have seen is there has been less and less things, items on the agenda. And part of the reason for that I have to say is the Division and the Department, all the work that they have done to
work with the industry. Their open door policy to allow, to meet with people to address issues. All of that I think has contributed to the success of the council. So I want to thank the Department, Mr. Dixon and Ms. Greene and everyone at the Division for all the work that they have done.

I always like to start the meetings by reading what the goals of the committee is and what the council is. So let me start by doing that. This is in Chapter 499.0121(1).

The council shall review, this part being Chapter 499, and the rules adopted to administer this part annually. Provide input to the Department regarding all proposed rules to administer this part, to make recommendations to the Department to improve the protection of the prescription drugs and public health. Make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of public health.

And that really speaks to what we have been
doing over the past eight years that I have been here.

I do want to introduce three new council members who have been appointed. Leaving the council are myself and Mr. Mike Ayotte, our Vice Chair, and also Mr. Bill Mahoney. And I want to thank Mike and Bill for their service on the council for all these years.

The appointments were just made like a week ago. So there wasn't time to allow the new members to officially be here, be on the council for this meeting, but they are in attendance today, or at least two I think are here. We may have the third come.

So it will be one from the pharmacy, representing the pharmacy at CVS, Mr. Bryan Files, and then for prescription drug wholesaler, Michael Mone, from Cardinal Health and Jeffery Toler from Wellgistics.

So Michael, do you want to introduce yourself and give everyone a little bit of background?

MR. MONE: Good morning. My name is Mike Mone, I am a pharmacist and an attorney. I have been with Cardinal Health about 10 years, but I actually started my career at then called BPR, then
it became DBPR, then it became BPR. I was a
prosecutor for many regulatory boards back then.
Left and went to the USP and spent a couple of
years setting standards at the USP. Came back to
the Attorney General's Office and worked for Bob
Butterworth as general counsel for a number of
regulatory boards. Left there, went to Kentucky as
the Executive Director of the State Board of
Pharmacy for 10 years.

Left there, went and taught at the Pharmacy
School at the University of Minnesota and then went
to Cardinal Health about 11 years ago, first at
Medicine Shoppe and then at Cardinal Health proper.

And thank you very much, I look forward to
working with you all and to come back to
Tallahassee and see a whole bunch of friends that I
don't get to see very often.

CHAIRMAN CACCIATORE: Thanks, Michael.

Mr. Toler.

MR. TOLER: Yes. My compliments to Michael,
that sounds like an impressive resumé. I started
in the business when I got out of college. I went
to grad school, I was recruited by a company called
McKesson, and then I got recruited by a company
called Cardinal. Worked for Cardinal for a decade
or better and then I went to run an Amerisource
company for a couple of years, and always in drug
distribution mainly.

Then I started off working for startup medical
services, both in manufacturing distribution,
logistics and I have doing that for about the last
eight years.

CHAIRMAN CACCIATORE: Welcome.

MR. TOLER: Thank you.

CHAIRMAN CACCIATORE: And if Mr. Files joins
us, Mr. Files was appointed as the retail pharmacy
representative replacing Mr. Ayotte and is employed
by CVS.

Next on the agenda is election of officers.

MR. DIXON: Mr. Chair, if we could take a
minute. We have got our Deputy Secretary here, Tim
Vaccaro. He is the Deputy Secretary responsible
for our Division.

We had a couple of presentations we want to
do, and I figured since we have him here, it would
be a good opportunity for us to do some
presentations for your guys who have been serving
our Division and who are departing since these are
your last meetings.

I first want to present Mr. Ayotte with a very
nicely wood grain, carved plaque which basically says, "Presented to Mike Ayotte, Vice Chair, in appreciation for your valuable leadership and service to the Florida Drug Wholesale Distributor Advisory Council." And it has got the dates on there from April 28th of 2008 to August 18th, 2016.

MR. AYOTTE: I look the same, don't I?

MR. DIXON: We don't have a picture.

MR. AYOTTE: Thank you. I will just take a point of personal privilege. This means an awful lot to me. I have been part of Florida for a long time and to me was here when the original, I guess when the drug issue occurred.

So to see where we are at today truly it is a credit to you and to everybody around this table, because we have changed a good part of the world and it really makes you feel proud. So thank you.

MR. DIXON: And last, but not least, to our esteemed Chair. This is presented to Gary Cacciatore, the Chair of the Drug Wholesale Advisory Board in appreciation for your valuable leadership and service to the Florida Drug Wholesale Distributor Advisory Council.

This date is also April 2008, to August 2016.

CHAIRMAN CACCIATORE: I knew it had been a
long time, but I didn't remember exactly how long.

MS. GREENE: We have Mr. Mahoney's and I will
send it to him.

MR. DIXON: Bill Mahoney is actually on the
phone. So he missed the meeting. When you miss
the meeting this is what happens.

MR. MAHONEY: Sorry about that, guys.

MR. DIXON: It is just a short drive. Thank
you so much for your service though.

MR. MAHONEY: Thank you for letting me be a
member of this, it has been a great organization
and such a great experience.

CHAIRMAN CACCIATORE: Yes, and let me echo
that as well. I mean, although I no longer live in
Florida, as many of you know I am originally from
Florida and have spent a lot of time here. And
although I do regulatory work throughout the
country for Cardinal Health, anytime there is an
opportunity to do things in Florida to serve
Florida I always jump at that because it is a
chance to come home actually. I appreciate that.

So next on the agenda we are going to do
election of officers. So we need to elect a Chair
and a Vice Chair. Only the current members of the
council should be eligible in voting at this time
since this is our last meeting. But you can't
nominate me since I am going off since I know you
guys like to do that.

So I am going to open the floor for
nominations. Should we do Chair or Vice Chair
first? Let's do the Chair first and get that out
of the way. So I am going to open the floor to
nominations.

MS. ELLIOTT: This is Dean Ellis. I would
like to nominate Steve Mays as our Chairman.

CHAIRMAN CACCIATORE: Steve, you are on the
phone I believe. Do you accept that nomination
with enthusiasm?

MR. MAYS: This is Steve. Sorry, I had myself
on moot. Yes, that is fine, I will accept that.

CHAIRMAN CACCIATORE: Thank you, Mr. Mays.

MR. MAYS: Unless there is someone else, I am
very definitely humbled by that.

CHAIRMAN CACCIATORE: Do I hear any further
nominations for Chair? You can nominate yourself
by the way.

MR. MAYS: This is Steve Mays. I would like
to nominate Dean Ellis.

CHAIRMAN CACCIATORE: Mr. Ellis.

MS. ELLIOTT: I think Steve would be a really
good candidate for it. I really do, Steve.

CHAIRMAN CACCIATURE: All right. I am not
going to force anyone to do that. So that sounds
like you are going to decline that nomination, Mr.
Ellis.

All right, hearing no further nominations, I
will entertain a motion to close nominations.

MR. HART: Motion.

MR. PHILLIPS: Second.

CHAIRMAN CACCIATURE: Motion by Peter Hart,
second by Mr. Phillips. No discussion. All in
favor signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATURE: Any opposed? All right,
motion carries. Nomination to close and now we get
to vote. All in favor of Mr. Steve Mays being
elected Chair, say aye.

(Chorus of ayes.)

CHAIRMAN CACCIATURE: Any opposed?

Congratulations, Mr. Mays.

MR. MAYS: I didn't have time to oppose.

CHAIRMAN CACCIATURE: Sorry, that was the
Chair's fault for not following the proper
procedure that time by the way.

MR. MAYS: I need to make sure I show up next
CHAIRMAN CACCIATORE: Yes. Listen, I know you are on vacation, so I appreciate you even calling in. So thank you.

We will open up the floor for nominations for Vice Chair. Really the Vice Chair just fills in when the Chair is not there. Mr. Mays indicated he would be at every meeting.

MR. MAYS: Yes, as long as my wife does a better job of scheduling vacation.

MR. BROCK: I nominate Jeenu Phillips.

CHAIRMAN CACCIATORE: Nomination by Mr. Brock of Jeenu Phillips.

MR. PHILLIPS: I will accept.

CHAIRMAN CACCIATORE: Jeenu says I will accept that nomination. Any further nominations?

MR. BROCK: May it be closed.

CHAIRMAN CACCIATORE: All right, nomination by Mr. Brock to close the nominations.

MR. HART: Second.

CHAIRMAN CACCIATORE: Second by Mr. Hart. Any discussion? All in favor of Mr. Phillips as Vice Chair signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed like sign.
Congratulations, Mr. Phillips.

MR. PHILLIPS: Thank you very much.

CHAIRMAN CACCIATORE: I believe the council is in very good hands going forward and I appreciate everyone stepping up to the plate to take on those leadership roles.

I am trying to think if I have anything else under the Chair's report. I do not believe so.

So I will now turn it over to Mr. Dixon to give us the Division Director's report.

MR. DIXON: Thank you. What you see on the agenda, we basically wanted to just go through our rulemaking to give you guys an idea of where we are at today.

We have gone through a lot. You will see that we did a lot working on out applications. Hopefully your permitting folks, if you do have an opportunity to talk to your permitting folks as they go through these, we would ask you if you have any questions or concerns about some of the new applications as we put them out there that you shoot us an e-mail or give us a call or something.

One of the things that we have tried to do is, we tried to put in what was statutorily required and only what was statutorily required that would...
help make those decisions.

So we are looking to get our deficiency rates down, applications so that the lower the deficiency rate the quicker you get someone in the business so you don't have people waiting around having products sit around. So most of our rulemaking deals with our applications.

We will start with 51N-1.001. That is the one on this report that doesn't necessarily deal with our applications. That is the rule that deals with our definitions. We recently had a rule workshop in Orlando. The basics, the two items that were addressed at that rule workshop was to get industry input both on the exception to wholesale distribution which allows retail pharmacies to distribute up to a certain amount.

The language that we provided set that amount at five percent based on the fact that was kind of the industry standard of what the FDA was going by as well.

The second issue on there was there was an exemption put in the statutes recently to allow for the distribution or movement of drugs between end stage renal pharmacies that are in end stage renal dialysis clinics that are in common owned

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
pharmacies.

And so what we wanted to do was to put some guidelines in place as to when those distributions actually were distributions which necessitated you having a license as opposed to the distribution for an emergency medical need, of immediate medical need for a patient.

So we did it centrally in Orlando and we got some feedback, we got some testimony. We have a transcript of it also. And based on having done that, we went ahead and proceeded with development of the language. So the language should be published and hopefully going into effect pretty soon.

With respect to the rest of the report, and one of the things, I don't know if you all noticed this, we actually tried to create a part two of 61N-2.001, and as we go through the applications, all of the applications will now be in 61-2. So what we are trying to do is eliminate a lot of the excess language and verbiage that deals with all of the different things and basically saying you have to submit a complete application and the fee, and then the application itself ask for all information.
So hopefully for your permitting folks, now you look at the application and see this is what I have to give and you don't have to kind of search through the different rules saying, okay, if you are here you need this, you need that, you need this. So the plan is hopefully by this time next year to have all of the applications done. We have done about a third of them, and we created a couple of new permits.

So when you look at this report, everything that is in blue, those applications are now effective. We highlighted which is kind of a light brown highlight, those are the rules that are open for development and those are the applications basically that we are working on.

Does anyone have a question about anything on the rules report?

I wanted to give you just kind of an legislative update. I am pretty sure by now everybody knows that Senate Bill 1604 went into effect. We are still working, we have pretty much implemented most of it. We have done training.

Some of the high notes that I think you guys would have noticed is the fact that the language is in there about the bond requirement, that if you
are a wholesale distributor and you distribute less than $10 million a year, the bond requirement is no longer $100,000, but it is $25,000. We have created the forms, the bond forms, and we have made them available. So if you want to go on our web page those bond forms are available.

As far as the language that deals with the implementation of the DQSA, that language is in place. We have had at least one meeting with the folks from the ACMA on some questions that have come up. So we are kind of reviewing some of their input to make sure our interpretation of our statute is consistent with what the federal authorities want.

One of the issues quite frankly is that sometimes the FDA is a little slow to move. So we do have a little bit of -- we have got a couple of challenges that we want to make sure that we don't get in front of them on some issues. But other than that everything has been going along smoothly.

Hopefully the wholesale application will be out there soon and that is the next big issue is to implement the renewal, so that instead of having you all, at least as wholesalers, renewing every year, we are going to try to get to a point where
wholesale permits are at least two years and then it will be staggered so that you won't have to have someone constantly in the stage of submitting a renewal application.

One of the things hopefully that your permitting folks would notice is that we are going to allow them if you have already submitted a personal information statement and it hasn't changed, just to submit an affidavit that your personal information statement hasn't changed along with the prior information statement.

So we hope that some of those changes will expedite the permitting process, and hopefully what you will see is that your folks will have a positive response to it. If not, that is definitely something we need to know about. We really haven't gotten any negative input right now, but if we do that is have something we can address pretty quickly. I mean, most of our units here, we have got a pretty small unit. So it doesn't take a lot for us to kind of respond to stuff.

CHAIRMAN CACCIATORE: Mr. Dixon, this is Gary Cacciatore. From my company's perspective the changes in the licensing and permitting process have been very well received.
MR. DIXON: Other than that we didn't really have any other updates or anything. But we are open to ask any questions that any of your council members might have.

MS. ELLIOTT: This is Dean Ellis. What time frame are you in on the renewal process as it relates to going from a year to two years?

MR. DIXON: Right now we are drafting the language on the rule. What complicates it a little bit, and quite frankly, I don't know that we anticipated this part of it, was as you know all your permits expire a year or two years from the end of the month or the date in which it was issued.

What that means is as far as the wholesalers you will all expire in a certain month during the year. So if we want to stagger those so that we don't have everybody renewing at the same time, we are contemplating saying, every other month will be a two-year permit, and then every other month after that will be a two-year permits. So only half of your permits will expire every year.

So it is a little complicated trying to write that language. We have got -- in one of the other areas of our department they have a rule that kind
of sets out the dates and time frames and things. It is in the professions area. It is a very good rule. It tells you when you renew and all these other things. So we are looking at doing something like that.

MS. ELLIOTT: Will the body of that application, is that going to change any or is that for some workshops later on?

MR. DIXON: The body of the application, the wholesale distributor application will change. It will -- some of the things like the primary versus the secondary wholesale distributor determinations, that is no longer necessary.

Some of the information with respect to like the picture. You only need a picture every, I want to say it is 180 days now, not every 30 days. Fingerprints, you are going to be able to submit your fingerprints electronically. So now you don't have to submit a fingerprint card.

So a lot of that we think will cut down on the days as far as the application. We need to kind of shore the application up, because some of the things on the application that are asked for are no longer necessary. So that is one of our primary focuses right now is to get the application.
MS. ELLIOTT: Thank you.

INVESTIGATOR GRIFFIN: As far as time frame I bet we will have a draft of the application next month. It is already open. So I would anticipate filing a rulemaking on the application itself probably in the next couple of weeks.

MS. ELLIOTT: Thank you.

CHAIRMAN CACCIATORE: This is Gary Cacciatore. Two things that come to mind. You mentioned the DQSA and the tracking, the federal tracking legislation. That is continually evolving waiting for guidance from FDA.

I had found it very helpful in the past when we have had updates on that, and I know in the industry we have people who track that. Someone in my group that is their full time job and Mr. Mays' company has someone as well and I think everyone does that. So bringing those people in is something to consider maybe for the next meeting. At least once a year to kind of see where things are, to get an update on what is happening on the federal level.

It might be a good idea I think for the next meeting to consider or maybe the next live meeting which would be the one after the next one. But
just to get an update on what is going on because that stuff is constantly changing with guidelines from the FDA. It is a 10-year implementation period on that law. We need to make sure we are staying up-to-date with that, make sure everyone is doing everything consistently, which I know the Department is doing that, but for the council I think it will be helpful to consider that.

And the other thing I just wanted to ask a question and Mr. Phillips might be able to assist with this being the Board of Pharmacy representative. I was at the Board of Pharmacy meeting, I think it was last week, and they were discussing 503-B pharmacies under the federal law which are the outsourcing facilities. For those of you who don't know, there is two parts to that DQSA.

There is the compounding part and then there is a track and trades part. Discounts mainly deals with the track and trades part, but for pharmacies, the compounding part of that federal regulation is a big issue as well.

The Board of Pharmacy is licensing those pharmacies that are not doing any patient specific medications in state. There was talk on the
sterile compound committee that they were creating
a sterile compounding permit for those facilities,
correct?

MR. PHILLIPS: I am not on that committee.

MR. DIXON: I can tell you what we know.

CHAIRMAN CACCIATORE: I was curious if they
interacted with you guys on that.

MR. DIXON: That is something that we watch
very closely and we look at really closely because
of two things. The 503-C -- I am sorry, the 503-B
facilities, they have to be run and supervised by a
pharmacist, but they do not have to be pharmacies.

CHAIRMAN CACCIATORE: Correct.

MR. DIXON: So I know the Board of Pharmacy
passed a statute that basically said if you are
outside of the state and you are distributing or
shipping sterile compounding products into the
state you have to have a non-resident sterile
compounding permit.

CHAIRMAN CACCIATORE: Correct.

MR. DIXON: If you are in the state I know
there are a couple of permits in the state. There
is a special sterile compounding pharmacy permit
that you get in the state, and there is other like
an interim sterile compounding permits as well that
are offered by the Board of Pharmacy.

I think the revolving issue probably in the next couple of years with that particular 503-B facility is going to be the fact that some of the facilities, and it is not just Florida, some of those facilities are not as aware that sterile compounding is not manufacturing. And sterile compounding by itself means that you are making a product that is different from what you start off with.

And you have some entities that may be repackaging as opposed to compounding. So I think that is going to be an issue because I know the federal government has put out some guidelines about those outsourcing facilities compounding as opposed to actually -- I mean, repackaging as opposed to actual conducting sterile compounding. So I know the FDA is working on that.

I know that from the Board of Pharmacy perspective we had some interactions with them as well from the perspective of trying to delineate where their jurisdiction starts and our jurisdiction stops.

CHAIRMAN CACCIATORE: And that was kind of my question. And I have seen this in other states. A
lot of those facilities do patient specific as well as non patient specific. If they're doing patient specific based on a prescription, they are licensed pharmacies.

MR. DIXON: Right.

CHAIRMAN CACCIATORE: But I have seen odd situations in other states where they have said that if they're not doing any patient specific, like you say they don't have to be a pharmacy then, so the State Board of Pharmacy in some states are saying, we not going to license them as a pharmacy.

And then you have similar to Florida a different agency that does manufacturing and they say they're not a manufacturer either. So no one is going to license them which is probably not a good idea and that is not happening in Florida.

But I just wanted to make sure those lines of who has got the jurisdiction are clarified and then you have got the repackaging issue it gets a little bit complicated.

MR. DIXON: Right, that is something that we are definitely drafting.

CHAIRMAN CACCIATORE: It occurred to me when I was at the Board of Pharmacy meeting. I wanted to make sure that the Department was involved and was
tracking those issues.

MR. PHILLIPS: I had another question.

CHAIRMAN CACCIATORE: Mr. Phillips, go ahead.

MR. PHILLIPS: I guess for those of you who
have experience around the country with multiple
states, Gary and Michael, maybe you can help. I
have a question for one of the pharmacists that
works in the state around donation of HIV
medications.

Do you know if any of the wholesalers ever
take back an redistribute those medications? Have
you heard of anything like that?

CHAIRMAN CACCIATORE: This is Gary Cacciatore.
When you say, take back?

MR. PHILLIPS: They donate them, you know,
those patients, the ones who have donated them back
so that they can be reused again. I was told that
there are some states that do that.

CHAIRMAN CACCIATORE: Mr. Mone, go ahead.

MR. MONE: This is Michael Mone. I can give
you some places to look. Both Kentucky when I was
there we drafted a regulation at the Board of
Pharmacy to be able to engage in that activity, and
Ohio as well has a regulation that allows the small
team distribution. It is never to a wholesaler.
It is going directly from the pharmacy to the charitable institution. It is going directly from the pharmacy to the physicians. It may in fact even be going overseas with the drugs. So there are rules that establish the policy and procedures around that as well as the recordkeeping requirements.

MR. ELLIS: The pharmacy regulation?

MR. MONE: The pharmacy regulation.

MS. ELLIOTT: This is Dean Ellis. Reggie, would that fall under the cancer donation program? Wouldn't those drugs --

MR. DIXON: No, sir. Our cancer donation program right now is benefit only to cancer drugs and those drugs that treat cancer.

MS. ELLIOTT: Okay. Thank you.

MR. MONE: It is really a legislative thing.

MS. ELLIOTT: You could expand the drugs on the donation list because there is a mechanism for cancer drugs you have to expand it to HIV drugs, that might be the best way to do that.

CHAIRMAN CACCIATORE: But to answer your question specifically, I think that Mr. Mone's point, I am not aware of that going through the wholesaler in other states. There is mechanisms...
and laws in other states that allow it to be
donated directly from pharmacy to be donated, take
them back into a pharmacy to be donated.

MR. DIXON: And if there is a specific issue
that you have or a scenario, we can talk about it
afterwards and we might be able to find someone to
assist you.

MR. MONE: I think it is that specific. It is
actually much wider spread where we have
pharmacists that handle a large number of HIV
population. And so there is a large number of
medications that go unused. This is something I
think could be helpful to a lot of people and
decrease the amount of waste that is happening.

CHAIRMAN CACCIATURE: Mr. Dixon, anything
else? We did have in our packet I thought we had
something from the self inspection report.

MR. DIXON: Yes, I am sorry. One of the
things that we are trying to do as an agency, our
division recently instituted our risk based
inspection program. What we are trying to do is
maximize our resources. Given the fact as you all
are aware, we only have a few inspections around
the state.

And so one of the things that we did was when
we put folks on the schedule and came up with our
program, we realized that it would be a while
before we got around to doing inspections of health
care clinic establishments.

And so what we decided to do instead of
necessarily having our inspectors go out and try to
some type of a surge or whatever you want to call
it, doing inspections of health care clinics, we
put together what is called a self inspection
survey.

And the purpose of the self inspection survey
is twofold. One, to conduct inspections of these
facilities, but also two, to kind of give them a
sense of a self-reflection of what they’re doing
and what the laws are changing and how that might
affect them.

We have gotten some questions from folks who
were not as aware of the changes to the DQSA. They
didn’t understand the difference between a product
versus a prescription drug because the definition
changed. So that was an opportunity for us to
provide education to folks without actually having
to go on-site and see them.

Our hope is to do that over the next couple of
years with all the health care clinic
establishments, and also to use that model to assist with inspections of out of date facilities, so that sometimes I know especially with wholesale distributors there is a provision that requires you to be inspected before or soon thereafter you getting your permit.

So we think that the self inspection may be a tool that some folks may be able to use and say, look, we have been inspected with the Department of Business Professional Regulation. If for whatever reason during the course of the self inspection there is an issue that comes up, then that is someone that we can go back out and determine on the risk base schedule to go out and do an in person inspection.

What we hope to do is facilitate more inspections of those folks that fall in our jurisdiction without actually being in a facility and disrupting business and that kind of thing. It also helps us better with our resources. So the folks that are in the lower categories of risks that we don't necessarily go out to that often, now we have been able to look at them, and we will get the surveys back and have some analysis of what they are doing and then decide who we actually do
need to inspect. If you have got someone who is purchasing drugs and don't even know it is a drug for instance. If I have a person who tells me medicine gas, medicine oxygen is a drug, those may be folks that we go back out and inspect. It has been real useful. We sent out about 500, but is was actually 300 and something e-mails that represented 500 facilities. So we have gotten pretty good response rate so far, but they still have about a month and a half to respond.

CHAIRMAN CACCIATORE: This is Gary. I think it is an excellent example of the Department really doing a good job of using their limited resources in a smart way. And just to remind everyone that the health care clinic establishments were set up because you have to sell to someone who is authorized to possess prescription drugs, and you have got clinics with multiple doctors sometimes and you can only sell to an individual doctor for use for their patients.

So sometimes you have one facility and each individual physician. So this allows a clinic or a health care establishment to get a license for the facility and can be used by any of the physicians at that facility. And it is lower risks I think
because there is less drugs there normally and they are under the supervision of a health care practitioner or physician or under the practitioner or someone there to store the drugs and watch the drugs.

So excellent example I think of using limited resources. So we will see how that goes.

MR. DIXON: We have gotten a pretty good response.

CHAIRMAN CACCIATORE: I was surprised to see how many health care clinic establishments there were. I didn't realize there was so many.

MR. DIXON: There are about 4,300 health care establishment facilities.

CHAIRMAN CACCIATORE: If I was a practitioner at one of those clinics I would rather have the clinic that has the responsibility for the products than my personal license. It makes a lot of sense if you are a practitioner in one of those facilities I believe.

MR. DIXON: I think the best thing about it is, and I think a lot of folks don't understand as a health care, if you have got three or four doctors in a health care clinic and they are purchasing under their own license, when you leave...
you take your drugs with you or you have to dispose of them. Because of this, now the doctor can leave and the drugs still belong to the clinic. So you don't have the kind of fight over what drugs belong to whom and we have seen that.

CHAIRMAN CACCIATURE: Yes, and I can tell you as a wholesale distributor we do have both. I mean, we still have a lot of places that we are selling to individual physicians at the address and you kind of wonder what the reason is for that. We open accounts both ways according to our licensing folks. Anythings else, Mr. Dixon?

MR. DIXON: I think the only other thing that we may have that may be of interest to folks is we did create -- well, two things, I take that back, I am sorry. We created a non-resident repackaging permit. I think it may not affect many, but there are some wholesale distributors, there are out of state wholesale distributors who only have the out of state wholesale distributor permit because we didn't offer a repackage permit.

So now if you are outside of the state of Florida and you have that wholesale distributor permit because all you did was repackage, now you can actually get a repackaging permit. You don't
have to have the $100,000 bond. You don't have to have the CDR. So we hope that is going to help some of those folks who specialize in repackaging to actually have a permit that fits their activity.

And you also have the virtual permits now. We are working on the applications for the virtual permits. And the virtual permits are there for those entities that previously had to get the prescription drug manufacturer permit and you really don't fit in there in the sense that you don't physically take the product.

You are more of an administrative office because you probably contract with somebody else to make your product and label it for you anyway. And so that virtual permit now allows you to get a permit that fits you. You don't have to comply with some of the physical requirements because you are not engaged in the possession of those prescription drugs. Someone else is making your product for you.

So we hope that those types of permits come about really from responses that we get from the industry about different things or things that we see during the course of our licensing folks. So we think that those permits will help a lot of
CHAIRMAN CACCIATORE: Thank you. Any questions for Mr. Dixon? Okay.

Turning to tab three. Other than setting our meeting dates for 2017, is there any other business that any of the other council members, questions that the council members that would like to raise? Any of our new council members?

If not, before we do the meeting dates, let me open up to comments or questions from the audience or the public. Anyone here in the room? Anyone on the phone would like to bring up an issue or ask any questions?

Okay. Hearing none, let's move on to setting of dates for 2017. The proposed dates in your packet on tab three. As you recall we do, traditionally you have to have at least one meeting per year in person. We decided over the last couple of years we are going to do two in person meetings, I believe in August and February.

If we want to stick with that schedule if there is okay with everyone. Ms. Greene is proposing some proposed dates of February 16th, May 18th, August 17th, and December the 7th.

Any council members have any particular --
know my calendar is full in December of next year.

MS. GREENE: Just as a note, session is a
regular session this coming year in Florida. It is
not early.

CHAIRMAN CACCIATORE: It is not early.

MR. HART: This is Pete Hart. A motion for
these dates.

CHAIRMAN CACCIATORE: There is a motion from
Mr. Hart, a second from Mr. Brock. Any discussion?
All in favor of setting those meeting dates signify
by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Any opposed like sign.

Any opposed like sign? The motion carries.

All right, if there is no further business I
will entertain a motion to adjourn.

MR. AYOTTE: So moved.

CHAIRMAN CACCIATORE: Moved by Mr. Ayotte.

MR. PHILLIPS: Second.

CHAIRMAN CACCIATORE: Seconded by
Mr. Phillips. All in favor signify by saying aye.

(Chorus of ayes.)

CHAIRMAN CACCIATORE: Thank you very much.

(Whereupon, the proceedings were concluded.)
CERTIFICATE OF REPORTER

I, CLARA C. ROTRUCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 02 through 37, is a true and correct record of my stenographic notes.

Dated this 11th day of October, 2016, at Tallahassee, Leon County, Florida.

______________________________
CLARA C. ROTRUCK
Court Reporter

Commission No.: FF 174037
Expiration date: November 13, 2018