

**State of Florida**  
**Department of Business and Professional Regulation**  
**Division of Drugs, Devices, and Cosmetics**

**Application for Permit as a Prescription Drug Manufacturer – Virtual**  
**Form No.: DBPR-DDC-235**

**APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.**

APPLICATION	APPLICATION REQUIREMENTS
<p><b>Application for Permit as a Prescription Drug Manufacturer - Virtual</b></p>	<p><input type="checkbox"/> Fee of \$1,650, which includes a \$1,500 <b>nonrefundable</b> biennial application fee and \$150.00 initial application /on-site 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.</p> <p><input type="checkbox"/> Make cashier's check, corporate check, or money order payable to the Florida Department of Business and Professional Regulation.</p> <p><input type="checkbox"/> If you answer "Yes" to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</p> <p><input type="checkbox"/> Sign and date the Affidavit section of the application.</p>
	<p>Mail completed application to:            Department of Business and Professional Regulation            2601 Blair Stone Road            Tallahassee, FL 32399-1047</p>

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.

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**Form No.: DBPR-DDC-235**

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
<input type="checkbox"/> New Application [3345/1020]
<input type="checkbox"/> 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
<b>TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER</b> 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: _____
<b>FULL LEGAL NAME</b> 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: _____
<b>FICTITIOUS, TRADE, OR BUSINESS NAME</b> 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. <input type="checkbox"/> The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above. <input type="checkbox"/> 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: _____.

<b>APPLICANT MAILING ADDRESS</b>			
Street Address or P.O. Box:			
City:	State:	Zip Code (+4 optional):	
County:	Phone Number:	Fax Number:	
<b>PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED (only if different from mailing address) Check <input type="checkbox"/> if not applicable</b>			
Street Address:			
City:	State:	Zip Code (+4 optional):	
County:	Phone Number:	Fax Number:	
Email Address:			
<b>APPLICATION CONTACT</b>			
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:			
City:	State:	Zip Code (+4 optional):	
Telephone Number:	Fax Number:		
E-Mail Address:			
<b>EMERGENCY CONTACT INFORMATION</b>			
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:			
City:	State:	Zip Code (+4 optional):	
Phone 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.

Mon ____:____ a.m./p.m. to ____:____ a.m./p.m.	Fri ____:____ a.m./p.m. to ____:____ a.m./p.m.
Tue ____:____ a.m./p.m. to ____:____ a.m./p.m.	Sat ____:____ a.m./p.m. to ____:____ a.m./p.m.
Wed ____:____ a.m./p.m. to ____:____ a.m./p.m.	Sun ____:____ a.m./p.m. to ____:____ a.m./p.m.
Thu ____:____ a.m./p.m. to ____:____ a.m./p.m.	

**Section III – Ownership Information**

**TYPE OF OWNERSHIP**

<input type="checkbox"/> Publicly Held Corporation	<input type="checkbox"/> Closely Held Corporation	<input type="checkbox"/> Limited Liability Company
<input type="checkbox"/> Charitable Organization—501(c)(3)	<input type="checkbox"/> Sole Proprietorship	<input type="checkbox"/> Government
<input type="checkbox"/> Partnership – General	<input type="checkbox"/> Professional Corporation or Association	<input type="checkbox"/> Professional Limited Liability Company
<input type="checkbox"/> Partnership – Other, Including Limited Liability Partnership and Limited Partnership	<input type="checkbox"/> 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):
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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:

	Street Address:	City:	State:	Zip Code:
3.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
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: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:

3.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name:	SSN/FEID/FEIN#	Date of Birth: <input type="checkbox"/> N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
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 <input type="checkbox"/> 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). <u>Note:</u> 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 <input type="checkbox"/> and write "N/A" in the lines below).				<input type="checkbox"/> Yes <input type="checkbox"/> No
Parent Company Name		% of Ownership		

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).			<input type="checkbox"/> Yes <input type="checkbox"/> No
Name:	Permit/License No.:	Issuing Agency:	

### Section IV – Background Questions

<b>BACKGROUND QUESTIONS</b>			
<p>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.</p> <p><b>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).</b></p>			
1.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> 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.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> 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.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> any affiliated party (defined above) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?
4.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> 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.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> 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.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant <b>or</b> 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

**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.).  <div style="text-align: right;"> <input type="checkbox"/> Permit/licensure list provided.  <input type="checkbox"/> No permits/licenses.           </div>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
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.).  <div style="text-align: right;"> <input type="checkbox"/> Permit/licensure list provided.  <input type="checkbox"/> No permits/licenses.           </div>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3a.	Name	Physical Address	Florida Permit/License Number



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.		
4a.	Name	Address	Florida Permit Number

### Section VII – Prescription Drug Manufacturing Activity

<b>MANUFACTURING ACTIVITIES</b>		
Generally identify the applicant's intended customers, the persons and entities that will purchase prescription drugs from the applicant establishment after permit issuance.		
<input type="checkbox"/> Manufacturers	<input type="checkbox"/> Wholesalers	<input type="checkbox"/> Pharmacies
<input type="checkbox"/> Hospitals	<input type="checkbox"/> Practitioners	<input type="checkbox"/> Health Care Clinics
<input type="checkbox"/> Veterinarians		
<input type="checkbox"/> Other (explain) _____		
Identify the types of prescription drugs that will be distributed by this virtual manufacturer establishment for which this establishment is considered the manufacturer.		
<input type="checkbox"/> Human Prescription Drugs	<input type="checkbox"/> Veterinary Prescription Drugs	
<input type="checkbox"/> Solid Dose		
<input type="checkbox"/> Liquids (Oral)	<input type="checkbox"/> Repackage – From Bulk as the manufacturer, not as a repackager	
<input type="checkbox"/> Injectables	<input type="checkbox"/> Repackage – From Stock as the manufacturer, not as a repackager	
<input type="checkbox"/> Topical		
<input type="checkbox"/> Dental		
<input type="checkbox"/> Ophthalmic		
<input type="checkbox"/> Compressed Medical Gases	<input type="checkbox"/> Refrigerated (Human, Veterinary, API or Otherwise)	
	<input type="checkbox"/> Frozen (Human, Veterinary, API or Otherwise)	
<input type="checkbox"/> Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):		
<input type="checkbox"/> Manufacturers	<input type="checkbox"/> Pharmacies for Compounding	<input type="checkbox"/> Other explain _____
Controlled Substances: Provide your DEA Number: _____ or check <input type="checkbox"/> No DEA Number		
Check Schedules: <input type="checkbox"/> Sch II <input type="checkbox"/> Sch III <input type="checkbox"/> Sch IV <input type="checkbox"/> Sch V		
Identify type of operation.		
<input type="checkbox"/> FDA Drug Application Holder (e.g. NDA, ANDA, BLA, NADA, ANADA holder)	<input type="checkbox"/> Co-licensed partner of the FDA Drug Application Holder	<input type="checkbox"/> Own Label Manufacturer
Provide your Federal Food and Drug Administration (FDA) drug establishment registration number.		
<input type="checkbox"/> FDA Establishment Registration Number: _____		
or		
<input type="checkbox"/> No FDA Establishment Number AND a written explanation is attached <input type="checkbox"/> .		
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	<input type="checkbox"/> Yes <input type="checkbox"/> No

	prescription drugs in Florida.)	
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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Are you submitting a product registration application and labels for your prescription drugs with this application?  Are the applicant's drugs manufactured outside of Florida? <input type="checkbox"/> Yes <input type="checkbox"/> No  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.  Written explanation attached? <input type="checkbox"/> Yes <input type="checkbox"/> No  <b>Note:</b> If you manufacture a prescription drug in Florida, you <b>CAN NOT SELL</b> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
5a.	Name and physical address where required records will be stored: Name:  Street Address:  City: _____ State: _____ Zip Code (+4 optional): _____	
6.	Will the required records be computerized, automated or stored electronically?  If yes, will you have a back-up procedure to be able to provide required records?  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?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No
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.  Alarm system description included? <input type="checkbox"/> Yes <input type="checkbox"/> No Security system description included? <input type="checkbox"/> Yes <input type="checkbox"/> No	
8.	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,	

	<p>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).</p> <p>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.</p> <p style="text-align: right;">Policy Attached?</p> <p>Receipt, security, storage, inventory, distribution/disposition of prescription drugs <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Distributing oldest approved stock first (FIFO) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Identifying, recording and reporting prescription drug losses and thefts <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Maintenance, retrieval and retention of required records <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Prescription drug recalls and withdrawals <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Natural disasters and other emergencies <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Segregation and destruction of outdated prescription drugs <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Temperature and humidity monitoring <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Product tracing and other DSCSA requirements <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
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.)	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Provide the date the establishment will be ready and available for inspection. <u>This is the earliest date the applicant may be deemed complete.</u>	___/___/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.

1.	<p><b>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?</b> 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.</p> <p align="right">List of applications/licenses attached? <input type="checkbox"/> Yes <input type="checkbox"/> No Copies of approval letters attached? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	<p><b>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?</b> 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.</p> <p align="right">List of licenses attached? <input type="checkbox"/> Yes <input type="checkbox"/> No Copies of licenses attached? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	<p><b>Does the applicant “manufacture” drugs or biologics that are not the subject of an approved FDA application or license?</b> If yes, please provide:</p> <ol style="list-style-type: none"> <li>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;</li> <li>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.;</li> <li>c. Statement of reasoning for which the applicant claims the prescription drug can be marketed in the United States; and</li> <li>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.</li> </ol> <p align="right">Labeling attached? <input type="checkbox"/> Yes <input type="checkbox"/> No Description of intent attached? <input type="checkbox"/> Yes <input type="checkbox"/> No Statement of reasoning attached <input type="checkbox"/> Yes <input type="checkbox"/> No Supportive documentation attached? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	<p><b>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?</b> 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.</p> <p align="right">Complete agreements attached? <input type="checkbox"/> Yes <input type="checkbox"/> No Agreements are considered trade secret? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

5.	<p><b>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?</b> If yes, please provide the following:</p> <p>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</p> <p>b. The name and address of the manufacturer or of the affiliate from whom the applicant obtains drugs or biologics.</p> <p style="text-align: right;">Relationship documents attached? <input type="checkbox"/> Yes <input type="checkbox"/> No  Documents are considered trade secret? <input type="checkbox"/> Yes <input type="checkbox"/> No  List of affiliates attached? <input type="checkbox"/> Yes <input type="checkbox"/> No  List of affiliates considered trade secret? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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**Section IX – Affidavit**

AFFIDAVIT	
<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
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