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

Application for a Non-Resident Prescription Drug Manufacturer
Form No.: DBPR-DDC-202

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

APPLICATION	APPLICATION REQUIREMENTS
Application for Permit as a Non-Resident Prescription Drug Manufacturer	☐ Submit fee of $1,000.00, made payable only by cashier's check or money order, to the Florida Department of Business and Professional Regulation. ☐ If you answer "Yes" to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation. ☐ Submit photocopy of your license/permit issued by your resident state that authorizes the sale and/or distribution of prescription drugs from the applicant's address. ☐ Sign and date the Affidavit section of the application.
	Submit the completed application with enclosures to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399

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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 [3326/1020]
☐ 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). [3326/1020]
Current Permit Number _____

Section II – Applicant Information

APPLICANT INFORMATION		
Federal Tax Identification Number:		
FULL LEGAL NAME		
Applicant's Full Legal Name:		
FICTITIOUS, TRADE OR BUSINESS NAME (applies only if different from full legal name)		
Full Fictitious, Trade or Business Name (sometimes "d/b/a" or "dba"): _____ Note: This name will appear on the permit and must be used on the applicant's operational documents for permitting activities. If the applicant intends to operate under a fictitious, trade or business name, provide the corresponding registration number from the Florida Secretary of State, Division of Corporations:_____		
APPLICANT'S MAILING ADDRESS		
Street Address or P.O. Box:		
City:	State:	Zip Code (+4 optional):
PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED		
Street Address:		
City:	State:	Zip Code (+4 optional):
County (if Florida address):	Country:	
E-Mail Address:	Phone Number:	Fax Number:

APPLICATION CONTACT			
Whom should the department contact with questions regarding this application?			
Last/Surname:	First:	Middle:	Suffix:
Address:			
City:		State:	Zip Code (+4 optional):
Telephone Number:		Fax Number:	
E-Mail Address:			

EMERGENCY CONTACT -INFORMATION			
Last/Surname:	First:	Middle:	Suffix:
Position/Title:			
Residence Street Address (must be different than establishment physical address):			
City:		State:	Zip Code (+4 optional):
Residence Phone Number:		E-Mail Address:	

OPERATING HOURS	
List Operating Hours – minimum 10 total per week (M-F) between 8:00 a.m. and 5:00 p.m., Eastern Standard Time, and at least 2 consecutive hours on at least 1 day:	
Mon _____:_____ am/pm to _____:_____ am/pm	Fri _____:_____ am/pm to _____:_____ am/pm
Tue _____:_____ am/pm to _____:_____ am/pm	Sat _____:_____ am/pm to _____:_____ am/pm
Wed _____:_____ am/pm to _____:_____ am/pm	Sun _____:_____ am/pm to _____:_____ am/pm
Thu _____:_____ am/pm to _____:_____ am/pm	

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.		
State:		

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General).
Name: **Address:**

List the name, position/title, date of birth and percentage of ownership, if applicable, for the applicant's owners, partners, members, managers, and corporate officers/directors.			
Name	Position/Title	Date of Birth	% of Ownership

List all trade or business names used by the applicant. Use additional sheet(s) if necessary.	

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership. Please note: A permit issued pursuant to this application is only valid for the applicant's name and applicant's address.)	☐ Yes ☐ No

Parent Company Name	% of Ownership

Does the applicant, the applicant's parent, sister or subsidiary companies, provide diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care? If so, please list all company/companies below. (Use additional sheet(s) if necessary).	☐ Yes ☐ No

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant or any "affiliated party" (defined below) been found guilty (regardless of adjudication) or pled nolo contendere in any jurisdiction of a violation of law that directly relates to a drug, device or cosmetic?
2.	☐ Yes	☐ No	Has the applicant or any affiliated party been fined or disciplined by a

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

The term "affiliated party" includes all of the following that may apply: the applicant's (i) directors, officers, trustees, partners, or committee members; (ii) any person who manages, controls or oversees the applicant's operations (does not have to be an employee), including the establishment manager and the next four (4) highest ranking employees responsible for prescription drug wholesale operations; and (iii) the five (5) individuals (natural persons) who own at least 5% of the applicant's stock ownership interest.

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

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 other 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, provide the name in which the permit is issued, the permit type, & permit number in the spaces provided below.)			☐ Yes ☐ No
1a.	Permit/License Name	Permit/License Type	Permit/License Number	
2.	Is the applicant licensed in any other state as a manufacturer, repackager, or wholesaler of prescription drugs? (If yes, list all states where licensed, including the license numbers and expiration date in the spaces provided below. Use separate sheet of paper if needed.)			☐ Yes ☐ No
2a.	State	Permit/License Number/Type	Permit/License Number/Type	Expiration Date
3.	Does the location for which you are applying 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
3a.	Name	Physical Address	Florida Permit/License Number	
4.	Does the location for which you are applying ship prescription drugs into Florida? (If no, provide the name and address of all locations that ship prescription drugs into Florida on your behalf in the spaces provided below. Use additional sheets if needed.)			☐ Yes ☐ No
4a.	Name	Physical Address	Florida Permit/License Number	

Section VII – Prescription Drug Manufacturing Activity

MANUFACTURING ACTIVITIES		
Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.		
☐ Manufacturers	☐ Wholesalers	☐ Pharmacies
☐ Hospitals	☐ Practitioners	☐ Clinics
☐ Veterinarians		

☐ Other (explain) _____

Identify the types of products the applicant will manufacture or distribute under this permit.

☐ 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: _____

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

Identify type of operation.

☐ Contract Manufacturer	☐ Own Label Manufacturer	☐ Limited Manufacturing Operations (Sterilizing, Encapsulating, etc.)

Provide your FDA establishment registration number.

FDA Establishment Registration Number:_____

Provide all National Drug Codes (NDCs) for all drug listings manufactured or distributed from the establishment. (Provide NDCs and drug listing on a separate sheet.)

NDCs and drug listings:_____

1.	Does your company sell and/or distribute only FDA approved drugs? (If no, explain on a separate sheet of paper.)	☐ Yes ☐ No
2.	Do you manufacture a prescription drug as a finished product? (If no, explain on a separate sheet providing accurate details.)	☐ Yes ☐ No
3.	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(17), Florida Statutes.)	☐ Yes ☐ No
4.	Do you intend to manufacture or distribute prescription drug samples? (If yes, a Complimentary Drug Distributor permit is required.)	☐ Yes ☐ No
5.	Do you understand that a repackager of prescription drugs is not considered a manufacturer for the purpose of this permit and that an Out-Of-State Prescription Drug Wholesale Distributor permit is required to wholesale repackaged drugs into Florida?	☐ Yes ☐ No
6.	Do you repackage prescription drugs?	☐ Yes ☐ No
7.	Do you understand that this permit only authorizes the distribution of prescription drugs made by you, or your client, and that if you sell and/or distribute a prescription drug made by another, you will be required to obtain	☐ Yes ☐ No

	an additional permit as an Out-Of-State Prescription Drug Wholesale Distributor?		
8.	Are you recognized by the FDA as a manufacturer of prescription drugs? (Please select below.)		☐ Yes ☐ No
8.a	___Own Label Manufacturer ___Contract Manufacturer ____ Other:_____		
9.	Do you comply with all Federal and State "Current Good Manufacturing Practices?		☐ Yes ☐ No
10.	Are you located outside the United States? (If yes, provide the name of each prescription drug you intend to import into Florida and attach documentation (Example: FDA Form 2656) from the United State Food and Drug Administration (FDA) giving you approval to do so. Use additional sheets.)		☐ Yes ☐ No
11.	Are products distributed under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)		☐ Yes ☐ No
12.	Are all required records stored and maintained at applicant's physical address? (If no, provide the establishments address where all required records will be stored and maintained below.)		☐ Yes ☐ No
13.	Physical address where required records are stored Street Address:		
	City:	State:	Zip Code (+4 optional):
14.	Are the required records computerized, automated or stored electronically? If yes, do you have a back-up procedure to be able to provide required records?		☐ Yes ☐ No ☐ Yes ☐ No
15.	Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion? (If yes, provide the types and descriptions of those systems on a separate sheet.)		☐ Yes ☐ No
16.	Is there a quarantine area at the applicant's establishment? (If not, please explain on a separate sheet.)		☐ Yes ☐ No
17.	Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's distributed products) to ensure safe storage? (If not, please explain on a separate sheet.)		☐ Yes ☐ No
18.	Does the applicant have written policies and procedures to include: 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 of outdated products; temperature and humidity monitoring?		☐ Yes ☐ No
19.	Have you attached a photocopy of your license/permit issued by your resident state that authorizes the sale and/or distribution of prescription drugs from the applicant address? (Note: If a license/permit is not needed in your state, you must comply with Rule 61N-1.015(6)(c), F.A.C.)		☐ Yes ☐ No

Section VIII– Qualify as a Manufacturer

QUALIFYING AS A MANUFACTURER (Check all that apply)		
1.	**Do you qualify as a "manufacturer" as a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic?**	☐ Yes ☐ No
2.	**Do you qualify as a "manufacturer" as the holder of an FDA-approved prescription drug application or biologics license?** If yes, list all biologics licenses and approved applications by number, and provide copies of no more than 5 FDA approval letters.	☐ Yes ☐ No
3.	**Do you qualify as a "manufacturer" as a private label distributor?** If yes, provide all agreements between you and any other manufacturer of a given prescription drug for which you are claiming to be a private label distributor, and a list of all NDCs and copies of all labeling for such drugs.	☐ Yes ☐ No
4.	**Do you qualify as a "manufacturer" pursuant to a co-marketing agreement or contract with another manufacturer?** If yes, provide a copy of your co-marketing agreement/contract.	☐ Yes ☐ No
5.	**Do you qualify as a "manufacturer" as an exclusive distributor for manufacturers that are members of your affiliated group as defined in Section 1504 of the Internal Revenue Code of 1986?** If yes, complete and provide the information and documents request under items A. – C. below.	☐ Yes ☐ No

A. Submit a copy of Parts I, II, and IV of the most recent Internal Revenue Service Form 851, Affiliations Schedule (Form 851) filed by the affiliated group's parent corporation, along with a copy of the certification/signature page(s) from the affiliated group's most recent consolidated tax return. If any of the information in Parts I, II or IV has changed since the Form 851 was filed, please submit a list of all such changes in the same detail required by Form 851.

B. Identify each affiliated group member identified on Form 851 above that qualifies as a "manufacturer" of prescription drugs under Section 499.003(31)(a), (b), (c) or (d), F.S. (a "source member"), and for each source member list the following:

1) Full corporate or entity name.
2) Principal place and address of business (mailing and physical).
3) State of incorporation or organization.
4) Any fictitious or trade name registered in Florida or to be used in connection with the distribution of prescription drugs in or into Florida.
5) Reference how the source member qualifies as a "manufacturer" – Section 499.003(31)(a), (b), (c) and/or (d), F.S.

C. In addition to the source members identified above, identify any other entities for which the applicant intends to distribute prescription under this permit. For each such person or entity, list the following:

1) Full corporate or entity name.
2) Principal place and address of business (mailing and physical).
3) State of incorporation or organization.
4) Any fictitious or trade name registered in Florida or to be used in connection with the distribution of prescription drugs in or into Florida.

If any entity identified in response to items B. or C. above is or was incorporated, organized or otherwise formed under the laws of any jurisdiction other than a state, possession or territory of the United States, including the District of Columbia and the Commonwealth of Puerto Rico, identify the foreign jurisdiction where each such entity was incorporated, organized or formed.

NOTE: You must advise the department in writing within (30) calendar days of any change of any

information contained or required to be contained in this source member list. This includes but is not limited to deletions and additions to source members for whom you distribute prescription drugs.

Section IX – Affidavit

AFFIDAVIT	
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 owner or corporate officer of the applicant without the need for witnesses unless otherwise required by law. I certify that I am empowered to execute this application as required by Section 559.79, Florida Statutes. 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:

*** 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.**

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399