

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

**Application for a Restricted Prescription Drug Distributor – Institutional Research**  
**Form No.: DBPR-DDC-212**

**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 Restricted Prescription Drug Distributor – Institutional Research</b></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Enclose the fee of \$600.00, made payable only by cashier's check or money order to the Florida's Department of Business and Professional Regulation.</li> <li><input type="checkbox"/> If the applicant answered "Yes" to any question in Section IV, enclose a detailed explanation along with any relevant documentation.</li> <li><input type="checkbox"/> Sign and date the Affidavit section of the application.</li> </ul> <p>Florida law generally defines "establishment" to mean a place of business at one general physical location. As used in this application, "the establishment" refers to the physical address of the establishment to be permitted.</p>
	<p>Submit the completed application with enclosures to:            Department of Business and Professional Regulation            2601 Blair Stone Road            Tallahassee, FL 32399-1047</p>

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**Application for Restricted Prescription Drug Distributor – Institutional Research**  
**Form No.: DBPR-DDC-212**

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 [3355/1020] <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). [3355/1020] 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 (only if applicant intends to operate under the permit under a name different from full legal name)		
Full Fictitious, Trade or Business Name (sometimes "d/b/a" or "dba"):		
<u>Note:</u> 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 for 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 (only if different from mailing address)		
Street Address:		
City:	State:	Zip Code (+4 optional):
County (if Florida address):	Country:	
E-Mail Address:	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 -RESIDENT INFORMATION			
Last/Surname	First	Middle	Suffix
Position/Title:			
Resident's Street Address (must be different than establishment physical address):			
City:		State:	Zip Code (+4 optional):
Resident's 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		
<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.		
<b>State or Country:</b>		

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General).			
Name:			
Address:			
City:		State:	Zip Code (+4 Optional):
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, 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.)			<input type="checkbox"/> Yes <input type="checkbox"/> No
Parent Company Name		% of Ownership	

**Section IV – Background Questions**

BACKGROUND QUESTIONS			
1.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> 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.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party 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 or any affiliated party 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 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	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> 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	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> 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.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
1a.	Permit/License Name	Permit/License Type	Permit/License Number

**Section VII – Prescription Drug Distribution Activity**

DISTRIBUTION ACTIVITIES		
Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant 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"/> Clinics <input type="checkbox"/> Veterinarians <input type="checkbox"/> Other (explain) _____		
Identify the types of products the applicant will manufacture or distribute under this permit. Check all that apply.		
<input type="checkbox"/> Human Prescription Drugs <input type="checkbox"/> Veterinary Prescription Drugs <input type="checkbox"/> Solid Dose <input type="checkbox"/> Repackage – From Bulk <input type="checkbox"/> Liquids (Oral) <input type="checkbox"/> Repackage – From Stock <input type="checkbox"/> Injectables <input type="checkbox"/> Topical <input type="checkbox"/> Refrigerated (Human, Veterinary, API or Otherwise) <input type="checkbox"/> Dental <input type="checkbox"/> Frozen (Human, Veterinary, API or Otherwise) <input type="checkbox"/> Ophthalmic <input type="checkbox"/> Compressed Medical Gases		
<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: _____		
Check Schedules: <input type="checkbox"/> Sch II <input type="checkbox"/> Sch III <input type="checkbox"/> Sch IV <input type="checkbox"/> Sch V		
1.	Are products distributed under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No

3.	Physical address where required records are stored Street Address:		
	City:	State:	Zip Code (+4 optional):
4.	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?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
5.	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.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Is there a quarantine area at the applicant's establishment?		<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	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?		<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Does the applicant understand all transfers of prescription drugs pursuant to this permit are limited to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with s. 240.241, F.S.?		<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Does the applicant understand that controlled substances may only be transferred to practitioners who have been issued a DEA number?		<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	Are all researchers who will be receiving prescription drugs pursuant to this permit located on the campus of the university or contracted campus locations of the university? (If no, the researcher must obtain an exemption letter from the Florida Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics in accordance with 499.03, F.S., and Rule 61N-1.011(4), F.A.C.).		<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Have procedures been established to ensure compliance with Rule 61N-1.023(6), F.A.C.?		<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	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?		<input type="checkbox"/> Yes <input type="checkbox"/> No
13.	Individual responsible for periodic monitoring of distributions, inventory reconciliation, inspections, and corrective actions.		
	Last/Surname	First	Middle
	Suffix		
	Address:		
	City:	State:	Zip Code (+4 Optional):
	Telephone Number:	Fax Number:	
	Email Address:		

**Section VIII – Affidavit**

<b>AFFIDAVIT</b>	
<p>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.</p> <p>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.</p>	
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  
2601 Blair Stone Road  
Tallahassee, FL 32399-1047