

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

Application for Restricted Prescription Drug Distributor – Institutional Research Permit
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
Application for Restricted Prescription Drug Distributor – Institutional Research Permit	<input type="checkbox"/> Enclose non-refundable biennial fee of \$600.00. <input type="checkbox"/> Make cashier’s check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation or DBPR. <input type="checkbox"/> If the applicant answered “Yes” to any question in Section IV, enclose a detailed explanation along with any relevant documentation. <input type="checkbox"/> Sign and date the Affidavit section of the application.
	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)5.f., 499.012(8)(o), 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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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
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).
Federal Tax Identification Number:
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”, 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: _____.
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:	
Telephone Number:	Fax Number:	
E-Mail Address:		
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:		
City:	State:	Zip Code (+4 optional):
Telephone Number:	Fax Number:	
E-Mail Address:		
EMERGENCY CONTACT		
The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department may contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to reach and communicate with the person listed.		
Last/Surname:	First:	Middle: Suffix:
Position/Title:		
Street Address:		
City:	State:	Zip Code (+4 optional):
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. The establishment must be open a minimum of 10 total hours per week (M-F) between 8:00 a.m. and 5:00 p.m., 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. <input type="checkbox"/> N/A (Partnership – General or Sole Proprietorship)				
State or Country:				
List the name and address of the applicant's registered agent for service of process in Florida (except Partnership – General or Sole Proprietorship) 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. <input type="checkbox"/> 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:
	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.				
1.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:

3.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name:	Social Security #:	Date of Birth:	% 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, 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 applicant 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			
<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>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).</p>			
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 above) 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 or 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.

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, and expiration date in the spaces provided below.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
1.a.	Permit/License Name	Permit/License Type and License Number	Expiration Date

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 establishment's 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.) Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Is there a quarantine area at the applicant's establishment? (If no, please explain on a separate sheet.) Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No		<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? (If no, please explain on a separate sheet.) Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No		<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. 1004.22, 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, Division of Drugs, Devices, and Cosmetics in accordance with s. 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

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 the applicant may only conduct business in Florida in the name of the dba.

I further understand that providing additional dba 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.

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
2601 Blair Stone Road
Tallahassee, FL 32399-1047