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

Application for Restricted Prescription Drug Distributor – Destruction Permit Form No.: DBPR-DDC-210

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 Restricted Rx Drug Distributor – Destruction	 Enclose the nonrefundable biennial fee of \$750.00, which includes \$600.00 application fee and \$150.00 initial application/on-site inspection fee. Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation or DBPR. If the applicant answered "Yes" to any question in Section IV, enclose a detailed explanation along with any relevant documentation. 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), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicants and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by §559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.

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

Application Restricted Prescription Drug Distributor – Destruction permit Form No.: DBPR-DDC-210

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 [3353/1020]

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). [3353/1020] 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 Employer Identification Number (FEIN):

FULL LEGAL NAME

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

Applicant's Full Legal Name:

FICTITIOUS, TRADE OR BUSINESS NAME

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

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

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

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

APPLICANT'S MAILING ADDRESS				
Street Address or P.O. Box:				
City:		State:	Zip Code (+4 optional):	
City.		State.	Zip Code (+4 optional).	
PHYSICAL ADDRESS OF ES	STABLISHM	ENT TO BE P	ERMITTED	
Street Address:				
City:		State:	Zip Code (+4 optional):	
City.		Siale.		
County (if Florida address):	Country	/:		
E-Mail Address:	Phone	Number:	Fax Number:	
		лст		
The application contact is the person that the dep			re are questions regarding the	
responses provided on or the documentation su				
also the person that will receive all official commu				
Last/Surname: First:		Middle:	Suffix:	
Address:				
City:		State:	Zip Code (+4 optional):	
Telephone Number:	Fax Nu	mber:		
E-Mail Address:				
EMERGENCY CONTAG			τιον	
The emergency contact is the person that the				
During an emergency, the department will conta	act this perse	on at times ou	utside of the regular business	
hours listed below. The contact information pro- reach and communicate with the person listed.	vided should	be sufficient	for the department to actually	
Last/Surname: First:		Middle:	Suffix:	
Position/Title:				
Street Address:				
City:		State:	Zip Code (+4 optional):	
Telephone Number:	F-Mail	Address:		
	ATING HOUR			
List the establishment's daily hours of operation in (M-F) between 8:00 a.m. and 5:00 p.m., and at le				
to circle "a.m." or "p.m." for each time indicated be		-		

Mon	:	am/pm_to		_am/pm	Fri:am/pm_to:am/pm
Tue_	<u> : : </u>	am/pm_to	:	am/pm	Sat: am/pm_to: am/pm
Wed _		am/pm_to	:	am/pm	Sun: am/pm_to: am/pm
Thu_	ŧ	am/pm_to		am/pm	

Section III – Ownership Information

TYPE OF OWNERSHIP							
Publicly Held Corporation	Closely I	Held Corporation		Limited Lia	ability Company		
Charitable Organization—501(c)(3)	Sole Pro	prietorship		Governme	ent		
🗌 Partnership – General	Profession	onal Corporation		Professior pility Com	nal Limited pany		
Partnership – Other, Including							
List the state of incorporation or state of c Proprietorship). Business entities organiz		on-U.S. laws list the	e coun	try of orga			
State or Country:							
Proprietorship or Partnership – General) Department of State, Division of Corp	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.						
Address							
		Ctoto		Zin Cod			
City		State		•	e (+4 Optional)		
member, manager, officer, director, chief operation of the business entity, as applic directors, limited liability companies would	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:
	t the name, social security number, date of re of the outstanding stock or equity intere		person who ow	ns 10 percent or
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:	Socia	I Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:		State:	Zip Code:
6.	Name:	Socia	I Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:		State:	Zip Code:
7.	Name:	Socia	I Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:		State:	Zip Code:
8.	Name:	Socia	I Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:		State:	Zip Code:
	all trade or business names used by the a all trade or business other trade or business				ssary. If the
Is the applicant a subsidiary of another company? (If parent companies with percentages of ownership, us necessary. <u>Note</u> : A permit issued pursuant to this a applicant and the applicant's name and address.)			ing additional shee	et(s) if	Yes No
Parent Company Name			% of Ownership		

Section IV – Background Questions

BACKGROUND QUESTIONS

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

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

1. 2.	☐ Yes If yes, explain in detail in Section V ☐ Yes If yes, explain in detail in Section V	□ 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? 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.	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?)

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 I Florida that authorize the purch applicant's establishment or ad permit is issued, the permit type spaces provided below.)	🗌 Yes 🗌 No					
1.a	Permit/License Name	Permit/License Type and License Number	Expiration Date				
2.	any other title for any activity re listing of all states where licens	other state as a manufacturer, wholesaler, or lated to prescription drugs? (If yes, provide a ed, including title of license, license number, ces provided below. Use additional sheets of	🗌 Yes 🗌 No				
2.a	State	Permit/License Types and License Number	Expiration Date				

Section VII – Prescription Drug Distribution Activity

DISTRIBUTION ACTIVITIES				
Generally identify the applicant's intended customers, i.e., the persons and entities that will utilize the applicant's services after permit issuance.				
 Manufacturers Hospitals Veterinarians Other (explain) 	Wholesalers Practitioners	 Pharmacies Clinics 		

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	Identify the types of products the applicant will take possession and arrange the destruction of under this permit. Check all that apply.						
□ Ac	Human Prescription Drugs Veterinary Prescription Drugs Solid Dose Repackage – From Bulk Liquids (Oral) Repackage – From Stock Injectables Repackage – From Stock Dental Refrigerated (Human, Veterinary, API or Otherwise) Ophthalmic Frozen (Human, Veterinary, API or Otherwise) Compressed Medical Gases Frozen (Human, Veterinary, API or Otherwise) Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers): Manufacturers Pharmacies for Compounding Controlled Substances: Provide your DEA Number:						
	Check Schedules: 🗌 Sch II			/			
1.	Are products distributed under permit may be required for free			2)			
2.	Are all required records store address? (If no, provide the records will be stored and ma	d and maintained at applic	ant's physical	YesNo			
3.	Physical address where requ Street Address:	ired records are stored					
	City:		State:	Zip Code (+4 optional):			
4.	Are the required records com If yes, do you have a back-up records?			lly? Yes No			
5.	Is the applicant's establishme entry after hours and a securi diversion? (If yes, provide the separate sheet.)	ty system protecting again	st theft and				
6.	Is there a quarantine area at	the applicant's establishme	ent?	Yes 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?						
8.	Does any of the applicant's owners, officers, or managers also own any interest in or hold any type of managerial relationship with a prescription drug wholesaler or prescription drug manufacturer? (If yes, disclose the person's name, position, and complete details of the relationship, including the name and address of the wholesaler or manufacturer in the spaces provided below. Use additional sheets of paper if needed.)						
8.a.	Name, Position, and	Name and Address	of Wholesaler or				
5.01	Relationship	Manufac	turer	Number			
9.	Is there a prescription drug m adjacent (next to) the applica		g establishment	Yes No			

10.	Identify the destruction activities the applicant will perform.	
	Transporting Prescription Drugs as a Contract Carrier	
	Warehousing Prescription Drugs Awaiting Destruction	
	Destroying Prescription Drugs through: Incineration Burying Other:	
11.	Is the applicant responsible for preparing the "Certificate of Destruction?" (If no, indicate on the line below who is responsible.)	Yes No
12.	Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription	🗌 Yes 🗌 No
	drugs; identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; natural disasters and other emergencies; segregation and destruction of products?	
13	Does the applicant understand that controlled substances must be handled in accordance with D.E.A. rules and regulations?	☐ Yes ☐ No
14.	Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete.	/ /20

Section IV- 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 Applicant:	Date:
Print Name:	Title:

Mail completed application to:

Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047