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

Application for Permit as a Prescription Drug Repackager
Form No.: DBPR-DDC-203

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 Prescription Drug Repackager	☐ Enclose the fee of $1,650.00, which includes a $1,500.00 **nonrefundable** biennial application fee and $150.00 initial application/on-site inspection fee. If the establishment is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit with the highest fee. ☐ Make cashier's check, corporate check, or money order payable to the Florida Department of Business and Professional Regulation. ☐ If you 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)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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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 [3328/1020] ☐ 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). [3347/1020] Permit Number under previous ownership: _____

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).
Applicant's TIN/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", "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.
☐ 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 MAILING ADDRESS		
Street Address or P.O. Box:		
City:	State:	Zip Code (+4 optional):
Email Address:	Telephone Number:	Fax Number:
PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED (only if different from mailing address) Check ☐ if not applicable		
Street Address:		
City:	State:	Zip Code (+4 optional):
Email Address:	Telephone Number:	Fax Number:
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):
Email Address:	Telephone Number:	Fax Number:
EMERGENCY CONTACT INFORMATION		
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):
Email Address:	Telephone Number::	Fax Number:

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

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.
☐ 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):

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, TIN/FEIN and percentage of ownership and check the box labeled "N/A" for date of birth.				
1.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
3.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ N/A	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name:	SSN/TIN/FEIN#	Date of Birth: ☐ 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 ☐ 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). Note: 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 ☐ and write "N/A" in the lines below).	☐ Yes ☐ 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 your residing state's regulatory authority. (Use additional sheet(s) if necessary).	☐ Yes ☐ No

Name:	Permit/License No.:	Issuing Agency:

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.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** 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.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** 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.	☐Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** any affiliated party (defined above) 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 (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.	☐Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** 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.	☐ Yes If yes, explain in detail in Section V	☐ No	Has the applicant **or** 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 other permits or licenses.). ☐ Permit/licensure list provided. ☐ No permits/licenses.	☐ Yes ☐ 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.). ☐ Permit/licensure list provided. ☐ No permits/licenses.	☐ Yes ☐ No

Section VII – Prescription Drug Repackaging Activity

REPACKAGING ACTIVITIES

Generally identify the applicant's intended customers, the persons and entities that will purchase or receive repackaged prescription drugs from the applicant after permit issuance.

☐ Manufacturers ☐ Wholesalers ☐ Pharmacies
☐ Hospitals ☐ Practitioners ☐ Health Care Clinics
☐ Veterinarians
☐ Other (explain) _____

Identify the types of prescription drugs the applicant will repackage or distribute under this permit. Check all that apply.

☐ 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: _____ or check ☐ No DEA Number

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

Identify type of operation.

☐ Contract Repackager – does not take title to drugs that are repackaged.	☐ Own Label Repackager - takes title to drugs that are repackaged.

Provide your Federal Food and Drug Administration (FDA) drug establishment registration number. **Please note**, an FDA drug establish registration **is not the same as** an FDA 503B Outsourcing Facility registration.

☐ FDA Drug Establishment Registration Number:_____
or
☐ No FDA Drug Establishment Number AND a written explanation is attached ☐.

1.	Are prescription drugs to be distributed under this permit intended for export? (Note: A permit may be required for Florida recipients that are freight forwarders handling prescription drugs in Florida.)	☐ Yes ☐ No

2.	Will all required records be stored and maintained at applicant's physical address? (If no, provide the name and address of the establishments where all required records will be stored and maintained under question #2a.) Please use additional sheets if necessary.	☐ Yes ☐ No
2a.	Name and physical address where required records are stored Establishment name:	
	Street Address:	
	City: / State: / Zip Code (+4 optional):	
3.	Will the required records be computerized, automated or stored electronically?	☐ Yes ☐ No
	If yes, will you have a back-up procedure to be able to provide required records?	☐ Yes ☐ No
	If electronically stored and maintained as a scanned image, is the electronic data maintained unchanged from the time of creation, receipt, purchase or distribution, depending on the document type?	☐ Yes ☐ No
4.	Is there a quarantine area at the applicant's establishment? (If no, complete below and provide a written explanation on a separate sheet.) Explanation included? ☐ Yes ☐ No	☐ Yes ☐ No
5.	Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's repackaged and distributed prescription drugs) to ensure safe storage?	☐ Yes ☐ No
	Does the applicant establishment have adequate temperature and humidity monitoring recording devices or logs to document proper storage of prescription drugs?	☐ Yes ☐ No
6.	Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details). **Note**: You **CAN NOT SELL** a product that you repackage at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division. Explanation included? ☐ Yes ☐ No ☐ N/A	☐ Yes ☐ 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? ☐ Yes ☐ No Security system description included? ☐ Yes ☐ No	
8.	Sections 499.01(2)(a)1. and 499.0121(8), F.S., requires repackagers 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, 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 documentation of outdated prescription drugs; temperature and humidity monitoring; and product tracing and other requirements under the federal Drug Supply Chain Security Act (DSCSA) or 21 USC 360eee-1.	

	Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy and procedure for recalls could be labeled or identified as "Recall Policy and Procedure"" or in another manner similar to this example. Policy Attached? Receipt, security, storage, inventory, distribution/disposition of prescription drugs ☐ Yes ☐ No Distributing oldest approved stock first (FIFO) ☐ Yes ☐ No Identifying, recording and reporting prescription drug losses and thefts ☐ Yes ☐ No Maintenance, retrieval and retention of required records ☐ Yes ☐ No Prescription drug recalls and withdrawals ☐ Yes ☐ No Natural disasters and other emergencies ☐ Yes ☐ No Segregation and destruction of outdated prescription drugs ☐ Yes ☐ No Temperature and humidity monitoring ☐ Yes ☐ No Product tracing and other DSCSA requirements ☐ Yes ☐ No	
9.	Do you intend to repackage and or distribute (directly or indirectly through your agents, employees or independent contractors) prescription drug samples? (If yes, a Complimentary Drug Distributor permit is required.)	☐ Yes ☐ No
10.	Does the applicant establishment intend to sell or distribute into Florida prescription drugs that the establishment does not repackage? (If yes, you will need an Out-of-State Prescription Drug Wholesale Distributor permit or other applicable permit under section 499.01, F.S. depending on your activities.)	☐ Yes ☐ No
11.	Provide the date the establishment will be ready and available for inspection. <u>This is the earliest date the application may be deemed complete.</u>	__/___/20__

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 OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A. 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. 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
Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047