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

Application for Permit as a Prescription Drug Manufacturer Form No.: DBPR-DDC-201

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 Manufacturer	Fee of \$1,650.00, which includes \$1,500.00 application fee and \$150 initial application/on-site inspection fee. If 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 or money order payable 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. Sign and date the Affidavit section of the application.
	Mail completed application to:
6	Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399

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.

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

Application for Permit as a Prescription Drug Manufacturer Form No.: DBPR-DDC-201

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.

CHECK ONE OF THE APPLICATION TYPES

Section I – Application Type

 New Application [3320/1020] 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). [3320/1020] 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).
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 MA	ILING A	DDRESS	
Street Address or P.O. Box:			
City:		State:	Zip Code (+4 optional):
PHYSICAL ADDRESS OF ESTA			
(only if different from mailing ad Street Address:	aress) c	леск 🔝 п посарр	DIICADIE
			= 0 1 (1 0 0
City:		State:	Zip Code (+4 optional):
County (if located in Florida):	Countr	y:	
E-Mail Address (Optional):	Phone	Number:	Fax Number:
APPLICATIO	N CON	ГАСТ	
The application contact is the person that the departr responses provided on, or the documentation submit also the person that will receive all official communications.	tted with,	the application. The the department re	he application contact is egarding the application.
Last/Surname: First:		Middle:	Suffix:
Address:			
City:		State:	Zip Code (+4 optional):
Telephone Number:	Fax Nu	ımber:	
E-Mail Address:			
EMERGENCY CONT	FACT IN	FORMATION	
The emergency contact is the person that the dep During an emergency, the department will contact thours listed below. The contact information provide reach and communicate with the person listed in the	this pers ed should	son at times outside d be sufficient for t	e of the regular business he department to actually
Last/Surname: First:		Middle:	Suffix:
Position/Title:			
Street Address:			
City:		State:	Zip Code (+4 optional):
Home Phone Number:	E-Mail	Address:	

	OPERATIN	IG HOURS		
List Operating Hours– minimum 10 total Standard Time, and at least 2 consecutive for each time indicated below.	per week (M	-F) between 8:00 a		
Mon	a.m./p.m. a.m./p.m.	Sat: a.r	n./p.m. to a.m./p.m. m./p.m. to a.m./p.m. m./p.m. to a.m./p.m.	
Section III – Ownership Information			^	
	TYPE OF O	WNERSHIP		
☐ Publicly Held Corporation	☐ Closely	Held Corporation	Limited Liability Company	
☐ Charitable Organization—501(c)(3)	☐ Sole Proprietorship		Government	
☐ Partnership – General	☐ Profess or Associat	ional Corporation tion	☐ Professional Limited Liability Company	
☐ Partnership – Other, Including Limited Liability Partnership and Limited Partnership	Other:			
List the state of incorporation or state of Proprietorship). Business entities organi	ized under no	on-U.S. laws list the		
State:				
List name and address of the applicant's Proprietorship or Partnership – General) Department of State, Division of Corpora registered with the Florida Department o	and provide ations' webpa of State, Divis	documentation, sugge, that the application of Corporations	ch as a print out from the Florida ant's registered agent is	
Name:		-		
Address:				

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

Social Security #:

Social Security #:

operation of the business entity, as applicable. For example, corporations would list officers and

City:

directors, limited liability companies would list members and managers, etc.

State:

Zip Code (+4 Optional):

% of Ownership:

% of Ownership:

Zip Code:

Date of Birth:

Date of Birth:

State:

Name & Title:

Street Address:

Name & Title:

City:

2.

	Street Address:	City:	State:	Zip Code:
				, p
3.	Name & Title:	Social Security #:	Date of Birth:	% of
٠.	Name & Tide.	Social Security #.	Date of Birtin.	Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name & Title:	Social Security #:	Date of Birth:	% of
				Ownership:
	Street Address:	City:	State:	Zip Code:
	Officer Address.	Oity.	Glate.	Zip Gode.
5.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
				Ownership.
	Street Address:	City:	State:	Zip Code:
6.	Name & Title:	Social Security #:	Date of Birth:	% of
				Ownership:
	Observed Addresses	0.4	Otata	7:- 0-4-
	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
) SE	Name & The.	Occurry #.	Date of Birtin	Ownership:
	Street Address:	City:	State:	Zip Code:
	the name, social security number, date of		person who ow	ns 10 percent or
mo 1.	re of the outstanding stock or equity intere		D-4f D:46	0/ of Oran analysis
1.0	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:
	olicel Address.	Oity.	Clate.	Zip Code.

3,	Name:	Social Security #:		Date of Birth:	% of Ownership:	
	Street Address:	City:		State:	Zip Code:	
4.	Name:	Socia	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	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:	
8.	Name:	Socia	Security #:	Date of Birth:	% of Ownership:	
	Street Address:	City:		State:	Zip Code:	
	t all trade or business names used by the a plicant does not use other trade or busines					
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).						
	ent Company Name		% of Ownership			

Is diagnostic, medical, surgical, or dental treatment of care services provided at the address of the establish permit application? If so, please list the name of the such services below. (Use additional sheet(s) if nece	☐ 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 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 below) 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 below) 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 below) 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 below) 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 below) 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: (i) the applicant's 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, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

Sec	Section V – Explanation(s) for "Yes" response(s) to background question(s)					
		EXPI	LANATIO	N		
			_			
			\			
Sec	tion VI – Other Perm	its or Licenses				
Sec	tion VI – Other Perm	its or Licenses PERMITS	OR LICE	NSES		
Sec	Are there any other provided that authorized	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no,	ed by any a ssion of pr	agency of the State escription drugs at	the	☐ Yes ☐ No
	Are there any other properties of the second strategy of the second seco	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no,	ed by any a ssion of pr please ch	agency of the State escription drugs at	the d	☐ Yes ☐ No it/License Number
1.	Are there any other properties of the second strategy of the second seco	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no, es below).	ed by any a ssion of pr please ch	agency of the State rescription drugs at eck this box an	the d	
1.	Are there any other properties of the second strategy of the second seco	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no, es below).	ed by any a ssion of pr please ch	agency of the State rescription drugs at eck this box an	the d	
1.	Are there any other properties of the second strategy of the second seco	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no, es below).	ed by any a ssion of pr please ch	agency of the State rescription drugs at eck this box an	the d	
1.	Are there any other provided that authorized applicant's establishment write "N/A" in the line Permit/Licent lis the applicant licent wholesaler of prescriptions.	PERMITS permits or licenses issue e the purchase or posses ment or address? (If no, es below).	ed by any a ssion of pr please ch Permi	agency of the State escription drugs at eck this box an t/License Type acturer, repackage where licensed, inc	Perm	
1. 1a.	Are there any other provided that authorized applicant's establishments "N/A" in the linear Permit/Licens wholesaler of prescription in the license numbers	permits or licenses issue e the purchase or posses ment or address? (If no, es below). cense Name sed in any other state as iption drugs? (If yes, list	Permi Permi s a manufa	agency of the State escription drugs at eck this box an t/License Type acturer, repackage where licensed, inc	Perm	it/License Number
1. 1a.	Are there any other provided that authorized applicant's establishment "N/A" in the line Permit/License applicant license numbers needed).	permits or licenses issue e the purchase or posses ment or address? (If no, es below). Deense Name Issed in any other state as iption drugs? (If yes, list and expiration date. Us	Permi Permi s a manufa	agency of the State escription drugs at eck this box an t/License Type acturer, repackage where licensed, ince e sheet of paper if	Perm	t/License Number ☐ Yes ☐ No

3.		otherwise physically transfer presc name, address, and Florida permit	
	Name	Address	Florida Permit Number
3а.			
Sec	tion VII – Prescription Drug Man	ufacturing Activity	
		ANUFACTURING ACTIVITIES	
Gen		ded customers, the persons and en	ntities that will purchase or
	eive products from the applicant after		titles that the parameters.
_	Manufacturers [Wholesalers	Pharmacies
	lospitals	☐ Practitioners	Clinics
_	/eterinarians		
	Other (explain)		Š
Iden	tify the types of products the applic	cant will manufacture or distribute ເ	under this permit.
	☐ Human Prescription Drugs ☐ Solid Dose	☐ Veterinary Prescription	n Drugs
	Liquids (Oral)	Repackage – From Bu	ulk
	☐ Injectables	Repackage – From St	tock
	☐ Topical		M. (dages A.D.) on Otherwice)
	☐ Dental		Veterinary, API or Otherwise)
	☐ Ophthalmic☐ Compressed Medical Gase		rinary, API or Otherwise)
∥ ,			\ (
L F	Ctive Pharmaceutical Ingredients (Manufacturers Pharmac	If yes, check the applicable box(es ties for Compounding	cplain
Con	trolled Substances: Provide your	DEA Number:	or check No DEA Number
	Check Schedules:	☐ Sch III ☐ Sch IV ☐	Sch V
Iden	tify type of operation.		
	Contract Manufacturer	Own Label Manufacturer	Limited Manufacturing Operations (Sterilizing, Encapsulating, etc.)
Prov	ride your Federal Food and Drug A	dministration (FDA) establishment	
	☐ FDA Establishment Registration	Number:	
o	or		
	☐ No FDA Establishment Number		

1.0	Are products distributed to be under this permit intended for permit may be required for freight forwarders handling pro		☐ Yes	☐ No	
2.	Do you manufacture a prescription drug as a finished product a separate sheet providing accurate details.)		☐ Yes	□No	
3.	Are you submitting a product registration application and I with this application? (If no, explain on a separate sheet p details). Note: You CAN NOT SELL a product that you manufacture until that product has been registered with the department before it is registered with the division is the basis for application and enforcement action by the division. Explanation included?	e shment uct	☐ Yes	□ No	
4.	Do you intend to manufacture or distribute prescription drug Complimentary Drug Distributor permit is required.)	ug samples? (If	yes, a	☐ Yes	☐ No
5.	Will all required records be stored and maintained at appli address? (If no, provide the address of the establishment records will be stored and maintained under question #5a	ired	☐ Yes	□No	
5a.	Physical address where required records will be stored: Street Address:				
	City:	State:	Zip Co	de (+4 opt	ional):
6.	Will the required records be computerized, automated or sold lf yes, will you have a back-up procedure to be able to proceed records?		ally? [☐ Yes [☐ Yes [□ No □ No
7.	Is the applicant's establishment equipped with an alarm sy after hours and a security system protecting against theft. (If yes, provide a written description of the alarm and securinclude: the type of system and how the system is monitor Description included? (If no, provide a written explanation of why the establishm with an alarm or security system.)	it] N/A	Yes [] No	
8.	Explanation included?			Yes	No
	Is there a quarantine area at the applicant's establishmen written explanation on a separate sheet.) Explanation included?	a			
9.	Will you distribute prescription drugs, including any active ingredient (API), used or intended for use in the manufact drug from the establishment? (For assistance in determin "distribute" see Section 499.003, Florida Statutes.)	pharmaceutical ure of a prescrip ing the definitior] Yes [] No
10.	Is the applicant's establishment equipped with adequate of (including refrigerated and freezing storage if appropriate distributed products) to ensure safe storage?		s [Yes [] No

200		
11,:	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
	(If no, provide written explanation for lack of specific policy or procedure identified above). Explanation attached? ☐ Yes ☐ No ☐ N/A	
	(If yes, provide a copy of each policy and procedure. 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 or procedure for receipt, security, storage, inventory could be labeled or identified as "Policy and/or Procedure for receipt, security, storage, inventory" or in another manner similar to this example.	
	Policies attached? Yes No N/A Policies labeled? Yes No N/A	
12.	Provide the date the establishment will be ready and available for inspection. This is the earliest date the applicant may be deemed complete.	//20*

Section VIII- Qualify as a Manufacturer

QUALIFYING AS A MANUFACTURER (Check all that apply)				
•	For the purpose of the questions below, the term "affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly: a. The business entity controls, or has the power to control, the other business entity; or b. Third party controls, or has the power to control, both business entities.			
•	FDA approvals must be in the name of the applicant as listed on this application. If the FDA approval is not in the same name as the applicant as listed on this application, you may not qualify as a manufacturer.			
1.	Does the applicant hold New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA) approved under the federal act? If yes, provide a list of all approved applications and licenses by number on a separate sheet, and provide copies of no more than 5 FDA approval letters. List of applications/licenses attached? Yes No Copies of approval letters attached? Yes No	☐ Yes ☐ No		
2.	Does the applicant hold a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262 for a drug or biologic? If yes, provide a list of the approved licenses by number on a separate sheet, and provide a copy of no more than 5 FDA licenses for drugs or biologics. List of licenses attached? Yes No Copies of licenses attached? Yes No	☐ Yes ☐ No		
3.	Does the applicant "manufacture" drugs or biologics that are not the subject of an approved FDA application or license? If yes, please provide: a. All labeling associated with the drug or biologics manufactured; b. A written description of the applicant's intent with respect to the drug or biologic, i.e., clinical trial, distribution or commercial sale, etc.; and c. Documentation that the drug or biologic can be legally placed into interstate commerce as per FDA regulations, for example, a copy of section(s) of the Code of Federal Regulations (CFR) denoting the product Drug Efficacy Study Implementation (DESI) designation or a copy of section(s) of the CFR denoting the product remains pending final DESI review, or a copy and summary of material(s) and authoritative literature reviewed during the applicant's investigation supporting that the product has not yet been reviewed in the DESI process. Labeling attached? Yes No Description of intent attached? Yes No Supportive documentation attached? Yes No	☐ Yes ☐ No		
4.	Is the applicant an affiliate of a person described in 1, 2, or 3 above that receives drugs or biologics directly from a person described in 1, 2, or 3 above or another affiliate of such person? If yes, please provide the following: a. If the applicant and the affiliate fall under the same business / organizational structure, i.e., one company is a parent, subsidiary, or sister / brother company of the other, provide written documentation describing the relationships between the companies, including, where applicable, the percentages of ownership that each company, e.g. an organizational chart; and b. The name, address, and Florida manufacturer permit, unless exempt from permitting, of the affiliate from whom the applicant receives drugs or biologics. Relationship documents attached? Yes No Documents are considered trade secret? Yes No List of affiliates attached? Yes No List of affiliated considered trade secret?	☐ Yes ☐ No		

5.	Is the applicant a co-licensed partner of a persabove who obtains drugs or biologics directly 2, 3, or 4 above or another co-licensed partner provide a complete, fully executed copy of no mobetween the applicant and the applicant's co-license.	r from a person described in 1, r of such person? Please re than 5 co-licensing agreement		
	Complete agreen Agreements are considere			
Section IX – 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 Applicant, Owner or Chief Executive:		Date:		
Print	Name:	Title:		

Mail completed application to:
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399