

State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics
 2601 Blair Stone Road, Tallahassee, Florida 32399-1047
 Phone: (850) 717 - 1800

PRESCRIPTION DRUG WHOLESALER
 OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER
 APPLICATION FOR A PERMIT UNDER
 THE FLORIDA DRUG AND COSMETIC ACT, CHAPTER 499, FLORIDA STATUTES

GENERAL INSTRUCTIONS: TYPE OR PRINT LEGIBLY an answer to every question. If a question does not apply to you, so state with N/A. If the space provided is insufficient, continue on page 10. You may make additional copies of page 10 if needed. Precede each response on page 10 with the question number to which the response applies. The person signing the application on behalf of the applicant must initial and date each page, as provided in the lower right corner. By placing initials on each page, the person is attesting to the accuracy and completeness of the information contained on that page.

Your establishment may not operate unless the permit is renewed timely.

 If applicable, current Florida Permit Number & Expiration Date

Application for:

 Name of Applicant Establishment (d/b/a name that will appear on permit and invoices)(limited to 41 characters)

 Physical Address of Establishment (street & suite number) This address should be reflected on invoices and / or shipping documents.

 Physical Address of Establishment (city, state, county and 9 digit zip code)

 Business Telephone Number

 Facsimile Number and/or Email Address for Regulatory Updates

 Mailing Address, if different (street & suite number)

 Mailing Address (city, state, and 9 digit zip code)

1. TYPE OF APPLICATION:

- a. New (you may not begin distributing prescription drugs in, into, or from Florida until a permit has been issued) A new permit is required for a change in ownership or controlling interest
- Renewal (to avoid the \$100 delinquent fee, your renewal application must be postmarked 45 days prior to the permit's expiration date)
- b. Prescription Drug Wholesaler (physically located in Florida)
- Prescription Drug Wholesaler – Broker Only (in FL & may not possess Rx drugs)
- Out-of-State Prescription Drug Wholesaler (located in another state or US Territory)

OFFICE USE ONLY			
	DEPOSIT	APPLICATION REVIEW	PERMIT ISSUED
Entity number	Cash Code:	App'd by:	_____ Permit No _____ Expiration Date
	Deposit Date:	Date:	
	Deposit No.:	Denied:	
	Check Amt.:	Notified date:	
Receipt Code	Bond:	Final date:	

- e. Do you (or an affiliated group member) own the property on which your establishment is located? YES NO

If yes, attach a copy of the recorded deed for the property on which your establishment is located. If no, attach a copy of the lease for the property on which your establishment is located. This lease must have an original term of not less than 1 calendar year.

- f. Has the applicant: (any yes response must be discussed in detail)

For a renewal application, respond based on information since your previous application submission.

- 1) Been found guilty (regardless of adjudication or pled nolo contendere in a court in Florida or any other jurisdiction of a violation of law that directly related to a drug, device or cosmetic? YES NO
- 2) Been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Ch. 499, F.S.? YES NO *For a renewal application, respond based on when notification or final disposition of the offense occurred, not according to the date of the offense.*
- 3) Been convicted of any felony under a federal, state (including Florida), or local law? YES NO
- 4) 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? YES NO
- 5) Been denied a permit or license related to an activity regulated under Ch. 499, F.S., in any state? YES NO

- g. Business Hours. (Note: A prescription drug wholesaler (including broker only) must designate a minimum of 20 hours weekly between the hours of 8:00 a.m. and 5:00 p.m. EST, Monday through Friday, and at least one day of the week provide for four consecutive hours.)

Monday – Friday _____ to _____ OR

Monday _____ to _____; Tuesday _____ to _____; Wednesday _____ to _____; Thursday _____ to _____; Friday _____ to _____

3. PRESCRIPTION DRUG ACTIVITIES:

- a. 1) Check all boxes that apply to your intended wholesale distribution activities in, from or into Florida.

- | | | | |
|--|--|---------------------------------|--------------------------------|
| <input type="checkbox"/> Human Injectable | <input type="checkbox"/> Dental | | |
| <input type="checkbox"/> Human other than injectable | <input type="checkbox"/> Ophthalmic | | |
| <input type="checkbox"/> Compressed Medical Gases | <input type="checkbox"/> Veterinary Legend | | |
| <input type="checkbox"/> Prepacked / Repackaged Medications to Physicians (for physician dispensing) | | | |
| <input type="checkbox"/> Repackaged Medications for Hospitals or clinics | | | |
| <input type="checkbox"/> Medical Devices containing prescription drugs | | | |
| <input type="checkbox"/> Controlled Substances Provide your DEA Number _____ | | | |
| <input type="checkbox"/> Sch II | <input type="checkbox"/> Sch III | <input type="checkbox"/> Sch IV | <input type="checkbox"/> Sch V |

2) Do you sell or intend to sell Active Pharmaceutical Ingredients (APIs) into Florida?
YES NO

If yes, check the applicable box(es) for your APIs customers:

Manufacturers Pharmacies for Compounding Other explain: _____

3) To what type of Florida customers do you intend to distribute prescription drugs?

Manufacturers

Pharmacies

Wholesalers

Hospitals

Practitioners

Clinics

Other (explain) _____

4) Do you export or intend to export prescription drugs? YES NO

b. Does the applicant

own and sell prescription drugs? YES NO

ever take possession of prescription drugs? YES NO

physically transfer prescription drugs to your customers? YES NO

If no, provide the name(s) and addresses from which the Rx drugs are shipped.

c. Do you understand that you can only sell / transfer drugs from, in, or into Florida that are the subject of an approved application that has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce?
YES NO

d. Are there any other licenses or permits issued by Florida or any other state to this applicant or to the applicant's address that authorize the purchase or possession of prescription drugs? YES NO

If yes, provide a list of all licenses and permits, including the name and address to which the license or permit is issued, the state and agency that issued the license or permit, the type of license or permit, the license or permit number, and the expiration date.

e. Are you a member in any group purchasing organization or do you intend to join a group purchasing organization within the next 12 months? YES NO

Indicate here if you are claiming this information is trade secret.

If yes, provide the name of the group purchasing organization(s), the name of the class of trade in which you will participate, and the definition of that class of trade as published by the group purchasing organization.

f. Have you included a written list of all wholesale distributors and manufacturers from whom you purchased prescription drugs in the last year and do you agree to provide updates to the department within 10 days after any change or additions? YES NO

Indicate here if you are claiming this information is trade secret.

g. Records related to the wholesale distribution of prescription drugs.

- 1) Are the records required to be maintained under Chapter 499, F.S., automated?
YES NO
- 2) Do you have a back-up procedure to be able to provide required records?
YES NO
- 3) If your records are stored electronically, does your system store the record as originally created without unauthorized updates? YES NO
- 4) Where will the required records be stored and maintained? _____
- 5) If you are physically located in Florida, are your records immediately available and easily retrievable for inspection at the time of the inspection? YES NO

h. For an application for a **new** permit, answer the following questions.

- 1) What is your estimated annual dollar volume of prescription drug sales for the following year? \$ _____
- 2) Do you sell or intend to sell anything other than prescription drugs in the following year? YES NO
Indicate here if you are claiming this information is trade secret.

If yes, complete the following formula:

$$\frac{\$ \text{_____}}{\text{annual Rx sales (answer to question 1 above)}} \div \frac{\$ \text{_____}}{\text{annual total company sales (all product lines)}} = \text{. _____}$$

- 3) What is your estimated annual dollar volume of purchases of prescription drugs for the following year? \$ _____ **Indicate here if you are claiming this information is trade secret.**
- 4) What is your estimated annual dollar volume of purchases of prescription drugs directly from the manufacturer for the following year? \$ _____ **Indicate here if you are claiming this information is trade secret.**

i. For an application to **renew** a permit, answer the following questions. Previous year means your tax year unless you designate another 12-month period that ends after your tax year. Alternate 12-month period _____ to _____.

- 5) What was your annual dollar volume of prescription drug sales for the previous year? \$ _____ **Indicate here if you are claiming this information is trade secret.**
- 6) Did you sell anything other than prescription drugs in the previous year? YES NO **Indicate here if you are claiming this information is trade secret.**

If yes, complete the following formula:

$$\frac{\$ \text{_____}}{\text{annual Rx sales (answer to question 5 above)}} \div \frac{\$ \text{_____}}{\text{annual total company sales (all product lines)}} = \text{. _____}$$

- 7) What was your annual dollar volume of purchases of prescription drugs for the previous year? \$ _____
Indicate here if you are claiming this information is trade secret.
- 8) What was your annual dollar volume of purchases of prescription drugs directly from the manufacturer for the previous year? \$ _____
Indicate here if you are claiming this information is trade secret.
- 9) What was your total dollar volume of prescription drug sales made in the previous 6 months? \$ _____
Indicate here if you are claiming this information is trade secret.
- 10) Attach 12 sales invoices for the wholesale distribution of prescription drugs by your permitted establishment dated within the previous year and at least three of these should be dated in the previous 6 months. (Note: If your establishment only ships prescription drugs, you may provide shipping documents instead of sales invoices.)
Indicate here if you are claiming this information is trade secret.

4. KEY PERSONNEL:

A Personal Information Statement Form, is required for each individual named in this section. Also for new applications and an initial renewal application, a fingerprint card and payment in the amount of \$47.00 for processing the fingerprint card is required for each individual named in this section.

- a. Provide the name of the manager of this applicant. _____
- b. Provide the name of the next four highest-ranking employees responsible for prescription drug wholesaler operations for the establishment and their position title or primary area of responsibility. *If you are a small business without an additional four employees 'responsible' for wholesale operations, provide the information requested for as many employees as applicable.*

Employee name	Position title or area of responsibility
1.	
2.	
3.	
4.	

- c. Provide the name and certification number of the designated representative(s) for this applicant. _____

- d. Provide the name of all shareholders who own at least 5 percent of the applicant and all affiliated parties for the applicant. Also provide the paragraph reference(s) that require identification of the person in this question.

An 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(4), F.S., or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(3), F.S.; or
- (d) The five largest natural shareholders who own at least 5 percent of the permittee or applicant. If the five largest shareholders fluctuate, provide the names as of the last record date for dividends.

- (z) Shareholder owning 5% or more of the applicant.

Name	Paragraph ref.

Name	Paragraph ref.

5. PRIMARY / SECONDARY WHOLESALER:

Are you a primary wholesaler? (Note: Primary Wholesaler Determination Form provides a definition of a Primary Wholesaler and Secondary Wholesaler and will help you determine whether you are a primary wholesaler or secondary wholesaler.)

YES NO

If yes, you must attach the completed Primary Wholesaler Determination Form.

If no, you must respond to the following questions.

- a. Identify the five largest shareholders of the corporation and their approximate percentage of ownership.

<i>Name</i>	<i>Est. % ownership</i>
1.	
2.	
3.	
4.	
5.	

b. If any of the responses to 5.a. are a corporation, provide the following information: corporate name, and the name, address, and title of each corporate officer and director for each such corporation.

Name	Address (street, city, state)	Title

c. Provide the name and address of all financial institutions in which the applicant has an account that is used to pay for the operation of the establishment, to pay for drugs purchased for the establishment, or in which deposits from the sales of prescription drugs are made. Identify all persons that are authorized signatories on each such account.

Indicate here if you are claiming this information is trade secret.

Name of Institution / Account #	Signatories
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

d. Identify the source of all funds and the amount of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is located. If any of these funds are borrowed, provide copies of all promissory notes or loans. For renewal applications, the applicant must identify sources of funding from individuals or privately held companies and the lead or primary financial institution responsible for providing credit to the applicant.

Indicate here if you are claiming this information is trade secret.

Amount	Source of Funds	Borrowed?
\$ _____	_____	_____
\$ _____	_____	_____
\$ _____	_____	_____
\$ _____	_____	_____

6. OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER:

Provide a photocopy of a valid license or permit issued by your resident state that authorizes the applicant to distribute (sell or transfer) prescription drugs into other states such as Florida. Have you attached a photocopy of the license or permit? YES NO
If your resident state does not authorize you to photocopy a license or permit, request the resident state complete a license verification for the applicant in lieu of the photocopy.

7. APPLICATION CONTACT:

Whom should the department contact with questions or follow-up on this application?

Name (last, first) Title Telephone Number

Mailing Address

Facsimile Number E-mail address

8. MISCELLANEOUS:

a. Mail the completed application and attachments to the Florida Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047

Make your check payable to the Department of Business and Professional Regulation.

b. Have you included evidence of the \$100,000 bond or security required by s. 499.012(2)(a) or (c), F.S.? YES NO

c. Have you submitted payment of the requisite application fees? YES NO
Prescription Drug Wholesaler (& Broker Only) \$800 renewal or \$950 for a new application
Out of State Prescription Drug Wholesaler \$800

d. How many personal information statements are you submitting with this application? _____

e. How many fingerprint cards are you submitting with this application? _____
Have you submitted \$47 for each fingerprint card? YES NO

f. Do you understand you cannot begin wholesaling prescription drugs in or into Florida until the permit is issued? YES NO

g. Do you agree to comply with Ch. 499, F.S. and Rule Chapter 64F-12, Florida Administrative Code related to the wholesale distribution of prescription drugs from, in, or into the state of Florida? YES NO

AFFIDAVIT

STATE OF _____

COUNTY OF _____

I _____, being duly sworn, depose and say I have read all questions, answers and statements on the foregoing Wholesaler Application and attachments and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement voluntarily with the knowledge that false or inaccurate information, misrepresentation or the failure to reveal information requested may be deemed sufficient cause for denial, suspension, or revocation of a wholesaler permit under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, for the establishment identified on page 1.

Signature of Owner or Corporate Officer

The foregoing instrument was sworn to before me this _____ day of _____, 20____ by _____ He/ she is _____ personally known to me or has produced _____ as identification.

Commission No. & Expiration Date:

Notary Public (Sign Name Here): _____

Notary Public (Print Name Here): _____

