Arkansas State Board of Pharmacy

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John Clay Kirtley, Pharm.D., Executive Director

Application for Wholesale Distributor of Prescription (Legend) Drugs Permit

PART I: GENERAL INFORMATION

Business Name:

DBA or name that will appear on your permit if different from Business Name above:

Federal Tax ID/ Employer Identification Number:

Physical Address of Applicant:

Street:

City: State: Zip:

Telephone Number: Fax Number:

Website:

Mailing Address (Complete this section ONLY if different from the physical address above.):

Street or PO Box:

City: State: Zip:

Person with whom the Board of Pharmacy may communicate regarding this application:

Name: Position:

Telephone: Email:

Type of Business (check all that apply):

- ☐ Manufacturer (inc. Virtual)
- ☐ Medical Gas Distributor
- ☐ Retail Pharmacy
- ☐ Sales/ Marketing
- ☐ Wholesale Distributor
- ☐ Jobber
- ☐ Hospital Pharmacy
- ☐ Business Office
- ☐ Repacker
- ☐ Warehouser
- ☐ Reverse Distributor
- ☐ Outsourcing (503B)
- ☐ 3PL
- ☐ Other - Please provide a description of your operation on a separate sheet.

Methods of Distribution (check all that apply):

- ☐ Products shipped directly to pharmacies
- ☐ Products shipped directly to physicians, dentists, podiatrists
- ☐ Products shipped directly to veterinarians
- ☐ Products shipped to distributors, wholesalers, repackers, jobbers
- ☐ Reverse distribution
- ☐ Business office only - does not distribute
- ☐ Other (Please explain on a separate sheet.)

Classes of Drugs Distributed (check all that apply):

- ☐ Legend drugs - human
- ☐ Legend drugs - veterinary
- ☐ Controlled substances - human
- ☐ Controlled substances - veterinary

Controlled Substances you Plan to Ship to Arkansas (check all that apply):

- ☐ Schedule II
- ☐ Schedule III
- ☐ Schedule IV
- ☐ Schedule V
- ☐ Not Applicable

DEA Number: ☐ Applied For ☐ Not Needed

Name of DEA Registrant:

FOR OFFICE USE ONLY

License #: WD Date Issued: Fee Submitted: Check #:

Is this application made as a result of a change of ownership? ☐ YES ☐ NO

If Yes, what is the name of the facility licensed by the Arkansas Board of Pharmacy?

_____

What is the permit number? _____

What is the expected closing date of the sale? _____

Who was the previous owner?

Has the applicant ever been licensed or permitted in Arkansas? ☐ YES ☐ NO

Does this business conduct operations at more than one location that ships drugs into Arkansas? ☐ YES ☐ NO

If Yes, are all facilities licensed in Arkansas? ☐ YES ☐ NO

How long has this location been engaged in the business of the wholesale distribution of drugs?

Does the applicant operate a warehouse or distribution center? ☐ YES ☐ NO

If Yes, has the facility been inspected by any regulatory/accrediting agency or board? ☐ YES ☐ NO

Does the applicant manufacture drug products? ☐ YES ☐ NO

If Yes, is the applicant registered with the FDA? ☐ YES ☐ NO

Does the applicant use a third party logistics provider? ☐ YES ☐ NO

If Yes, name and address of the provider:

Does the applicant serve as a third party logistics provider for another company? ☐ YES ☐ NO

If Yes, provide the name and address of the other company:

What products do you distribute for them? (You may attach a list on a separate sheet, if necessary.)

Does the applicant distribute medical gas only? ☐ YES ☐ NO

Does the applicant have a retail pharmacy license? ☐ YES ☐ NO

If Yes, does the applicant compound drugs? ☐ YES ☐ NO

Does the applicant distribute drug samples? ☐ YES ☐ NO

If Yes, please describe the samples and provide a general description of the recipients of these samples:

Please provide a general description of the products and operations of the applicant related to the wholesale distribution of legend drugs. You may attach a separate sheet if necessary.

PART II: APPLICANT HISTORY

Please answer each of the following questions by putting a check (√) in the appropriate box on the right. You must answer each question with a "Yes" or "No" response as no other response is acceptable. All "Yes" answers MUST be explained in detail in a separate SIGNED and NOTARIZED affidavit. The affidavit should include all relevant dates, and identify the relevant jurisdiction and/or entity involved. Failure to disclose any of the requested information may result in the denial of your application or other appropriate action.

NOTE: If you answer "Yes" to any of the questions below and you have already submitted a detailed affidavit to the Arkansas State Board of Pharmacy explaining your response you need not submit another detailed affidavit. Please note the date of your previous submission next to the applicable question(s).

Is the applicant currently under investigation in any state in which it is licensed?	☐ YES	☐ NO
Has the applicant ever been the subject of disciplinary action or been sanctioned by any licensing authority?	☐ YES	☐ NO
Is there any disciplinary action pending against the applicant by any licensing jurisdiction, the USDA, FDA, Drug Enforcement Agency or any state drug enforcement authority?	☐ YES	☐ NO
Has the applicant ever been convicted of violating any federal, state or local law related to drug samples, wholesale or retail drug distribution, or distribution of controlled substances?	☐ YES	☐ NO
Has the applicant ever been convicted of violating any federal, state, or local law related to the practice of pharmacy?	☐ YES	☐ NO
Have any of the applicant owners, officers, directors, or stockholders ever been convicted of a felony or crime involving the practice of pharmacy? (If the business is a corporation, you need not include stockholders in this question unless they currently serve as officers or directors of the applicant business, or own more than twenty percent (20%) of the company stock.)	☐ YES	☐ NO
Has any sanction or disciplinary action been taken regarding any license, permit or registration issued to the applicant, officers, directors, partners or stockholders involving drug distribution? (If the business is a corporation, you need not include stockholders in this question unless they currently serve as officers or directors of the applicant business, or own more than twenty percent (20%) of the company stock.)	☐ YES	☐ NO
Are there any charges pending against the applicant, officers, directors, partners or stockholders involving drug distribution? (If the business is a corporation, you need not include stockholders in this question unless they currently serve as officers or directors of the applicant business, or own more than twenty percent (20%) of the company stock.)	☐ YES	☐ NO

PART III: PERSONNEL

If this facility is a **503B outsourcing facility** engaged in the compounding of sterile drugs for human use, it shall have an Arkansas licensed Pharmacist in Charge on staff a minimum of 32 hours a week. Please provide the Arkansas license number for the Pharmacist in Charge of this facility. Please check here if this is **Not Applicable**: ☐

Name	License #	Hours/Week	Degree
Pharmacist in Charge:			

If the pharmacist is reciprocating to Arkansas, please check one of the following months to indicate the expected appearance before the Arkansas Board:

February ☐ **June** ☐ **October** ☐

✳ The Arkansas pharmacist in charge must hold an Arkansas pharmacist license and shall be an employee (not a consultant) of the applicant who is present at the physical location stated on the application. The Arkansas pharmacist in charge shall work a minimum of thirty two (32) hours per week. The Arkansas pharmacist in charge is responsible for compliance with Arkansas regulations as they pertain to the shipment of drugs to Arkansas patients and for receiving and maintaining publications distributed by the Arkansas State Board of Pharmacy.

PART IV: BUSINESS OWNERSHIP

Select the appropriate form of ownership from the choices below, and then go to the next appropriate section.

☐ Sole Proprietorship (Go to A)
☐ Corporation (Go to C)
☐ LLC (Go to C)
☐ Other (Please explain)
☐ General Partnership (Go to B)
☐ Limited Partnership (Go to B)
☐ LLP (Go to B)

A. Please provide the name, and the address of the owner of this company:

Go to Item D.

B. Partnership Name, if different from Applicant name listed on Page 1.

In the space provided below, please provide the names, addresses and percentage ownership of all partners/members. You may attach a list of partners/members if there is not enough space.

Go to Item D.

C. Corporation Name, if different from Applicant name listed on Page 1.

☐ Check if Subchapter S Corporation State of Incorporation/Formation:

Is this corporation publicly traded? ☐ YES ☐ NO

Is this corporation a wholly owned subsidiary of another company or corporation? ☐ YES ☐ NO

What is the name of the parent company?

Please provide the names, addresses and percentage ownership of all of the owners of this corporation. You may use a separate sheet if you need more space.

Go to Item D.

D. Please provide the names and titles of the officers or directors of this company.

President: _____

Vice President: _____

Secretary: _____

Treasurer: _____

Specify additional titles below: _____

_____

_____

_____

_____

If you need additional space for the corporate officer list, please attach the list as a separate document.

PART V: DOCUMENTATION

Attach copies of the following documents to this application, or an explanation of why these documents are not included:

- If the applicant is not located in Arkansas, **a copy of the license/permit issued by the state in which the wholesale distributor is located**. If you do not have a license in your home state, please provide a statement from your State Board of Pharmacy stating that you are not required to be licensed.

- If the applicant is not located in Arkansas, a copy of the **latest inspection report** of the facility issued by the regulatory agency that performs such inspections in the state in which the business is located. If the facility has never been inspected, a statement from the applicant stating that the facility has never been inspected.
- Copies of all **federal licenses or permits**. If you indicated that you will be shipping controlled substances (on page 1 of this application) you must provide a copy of your DEA and FDA permit. Please include a copy of your FDA Inspection and any other FDA documentation.
- A **current certificate of insurance** for this facility issued by your insurance agent, showing your product liability insurance, or general liability insurance if you do not carry product liability insurance. Do not send a copy of the policy – just the certificate of insurance.

PART VI: APPLICATION FEE

Check **one** of the following options:

☐ This is a new permit application.
If the application is submitted in an even-numbered year (2024, 2026, etc.), the fee is $300.00
If the application is submitted in an odd-numbered year (2023, 2025, etc.), the fee is $450.00

☐ This is a change of ownership of a current permit holder. The fee for a change of ownership is $150.00.

Please Note: The Arkansas Wholesale Distributor of Prescription (Legend) Drugs Permit is a biennial permit and expires on December 31st of even-numbered years. If a permit is issued during an even-numbered year it will be up for renewal later that year. Check your application to make sure it is complete and you have included all required documentation. Incomplete applications will delay processing. Your application will expire 1 year from date of receipt. Application fees will not be refunded.

PART VII: CERTIFICATION

Please read carefully and sign below.
I swear, or affirm, that all statements made herein and on the attached forms are true and correct. All of the provisions of Arkansas laws and regulations related to the wholesale distribution of drugs into Arkansas will be faithfully observed during the period any permit issued may be in force and effect.

This business employs adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs; meets the minimum requirements for the storage and handling of prescription drugs specified in Regulation 08-00-0008; meets the minimum requirements for the establishment and maintenance of prescription drug distribution records specified in Regulation 08-00-0008; has written policies and procedures as described in Regulation 08-00-000; maintains ownership/ management/employee records as specified in Regulation 08-00-0010; complies with all applicable federal, state and local laws and regulations; and, before shipping to a recipient in Arkansas, will determine that the recipient is appropriately licensed and authorized by law to purchase and possess prescription drugs.

I understand that the Arkansas Pharmacy Lawbook contains the statutes and regulations related to the wholesale distribution of drugs into Arkansas and is available online at the Arkansas State Board of Pharmacy website. I have read regulations 08-00-0001 through 08-00-0014 and will abide by them.

I will notify the Arkansas State Board of Pharmacy if any information contained in this application for a permit changes within thirty (30) days of the change.

By virtue of filing this application, I do solemnly swear or affirm that I am of good moral character, and that I understand the instructions and terms as set forth in this application form, that I have personally completed this form, that the information given in this application is true, correct and complete to the best of my knowledge. I authorize the Arkansas State Board of Pharmacy to review files pertaining to this application and related documents, and all law enforcement records, administrative records, and court documents to confirm the accuracy and completeness of the information provided herein. This application and signature shall act as authorization for entities in possession of applicable information to release such information to the Arkansas State Board of Pharmacy.

Signature of Owner/Representative: _____

Printed Name of the Owner/Representative: _____

Date: _____

Checks should be made payable to: Arkansas State Board of Pharmacy.

Return the completed application and all related documents and fees to:
Arkansas State Board of Pharmacy
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