TEXAS Health and Human Services

Texas Department of State Health Services

BUSINESS FILING AND VERIFICATION SECTION
OUT -OF-STATE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

OOS DRUG DIST –RX 2501

Initial / Renewal License Application

(Health and Safety Code, Chapter 431)
Return both the completed application, and non-refundable check or money order made payable to:
Texas Department of State Health Services,
Food & Drug Licensing,
PO Box 12008, Austin, Texas 78711

BUDGET: **ZZ114**
FUND: **183**
LICENSE #

Contact this office at (512) 834-6727 for assistance with the application.

Name Business is Conducted Under (DBA):_____

Physical Address to be Licensed: _____

City, County, State, Zip Code: _____

Telephone # at address: (____) _____

Type of Operation: (Check all that apply)

☐ 3PL ☐ Wholesale Distributor ☐ Medical Gas Distributor ☐ Own label distributor

☐ Broker ☐ Outsourcing Facility ☐ Charitable Drug Donor ☐ Other _____

Type of Drugs: (Check all that apply)

☐ Prescription ☐ Bulk Active Pharmaceutical Ingredient

☐ Biologics ☐ Nonprescription ☐ Veterinary ☐ Controlled Substance (DEA# _____)

FEE SCHEDULE FOR OUT-OF-STATE PRESCRIPTION DRUG WHOLESALERS

The fee schedule is based on gross annual sales for all drugs delivered into the State of Texas and wholesaled at the licensed place of business.

GROSS ANNUAL DRUG SALES			FEE FOR INITIAL/RENEWAL LICENSE OR CHANGE OF OWNERSHIP
Medical Gas ONLY Distributors	□ $ 0.00 - $ 20,000.00	=	$ 675.00 per facility
□ LV1	$ 0.00 - $ 199,999.99	=	$ 1,080.00 per facility
□ LV2	$ 200,000.00 - $19,999,999.99	=	$ 1,755.00 per facility
□ LV3	$ 20,000,000.00 - $ or more	=	$ 2,295.00 per facility

☐ **License Replacement Fee- $100.00**

Texas Administrative Code 229**:** A replacement license shall only be issued if lost, stolen or destroyed and license is current and valid at the time of the request, and no changes in business name, location or ownership have occurred.

□ **Late Fee** - A person who files a renewal application after the expiration date must pay an additional $100.00.

ADDITIONAL DOCUMENTATION REQUIRED: All documents must be submitted prior to issuance of license

(Medical Gas ONLY Distributors <u>are not required</u> to complete attachment A & B)

□ Copy of home state license.

□ A list of all licenses and permits issued to the applicant <u>by any other state</u> under which the applicant is permitted to purchase or possess prescription drugs. If applicant or firm is **<u>not</u>** licensed with other states, please check here: ☐

□ Completed Attachment A.

□ Required additional information as listed on Attachment B.

Exemption from license fee:

□ 25 TAC 229.427 - A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 501(c)(3), or a nonprofit affiliate of the organization**.** Please attach copy of 501(c)(3) with application.

VERIFICATION: I swear or affirm that all information in this application is true and correct. I further certify by signature hereon, that I am authorized to execute this document on behalf of the corporation and am eligible to receive a license. If signing this as owner of a sole proprietorship, I am not delinquent in the payment of any child support owed under Chapter 232, Family Code. If signing as a sole proprietor, I certify I have filed the assumed name certificate in appropriate counties pursuant to Business and Commerce Code, Chapter 36. I further certify that I have read and understand Chapter 431 of the Health & Safety Code, the applicable provisions of 25 Texas Administrative Code, Chapter 229, and agree to abide by them.

Print Name:	**Title:** □ Owner □ Partner □ President □ Corporate Designee / Agent
sign here►	**Date:**

PRIVACY NOTIFICATION: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. You may visit our website listed below for more information on the Privacy Notification (Reference: Government Code, Section 552.021, 552.023 and 559.004).

ALL SIX PAGES OF THE APPLICATION FORM <u>MUST</u> BE COMPLETED BEFORE A LICENSE WILL BE ISSUED. Please allow 4-6 weeks for processing**.**

Visit our website at: **www.dshs.texas.gov**

Please address **<u>correspondence only</u>** to:
Texas Department of State Health Services
Food and Drug Licensing Group, MC 2835
PO Box 149347
Austin, Texas 78714-9347

PURPOSE OF THIS APPLICATION: Mark appropriate box to indicate purpose of application, and/or any changes in status of firm. Initial licenses will expire two years from the date of payment receipt by the Department.

☐ **New** Start date of regulated activity: _____

☐ **Change of ownership:** If change affects multiple licensed locations, contact us at 512-834-6727. **Note** – if ownership name, EIN, DBA, & location are remaining the same, and the only change is the actual owner(s), please call our office prior to submitting this application. If this is a parent company change only, and the licensed information is not changing, call our office prior to submitting the application.

Previous owner: _____ Effective date: _____

Previous dba name: _____

Previous license number: _____

☐ **Amended**: If change affects multiple licensed locations contact us at 512-834-6727 prior to submitting application. The current expiration date remains in effect for amendment only.

☐ Location change (previous location): _____

☐ Name Change (previous name):_____

☐ Other: _____

Current license number: _____

Effective date of change: _____

☐ **Renewal**: Renewals are valid from the anniversary date. Failure to submit the renewal fee before the expiration date will result in a delinquency fee for each location and must be remitted before the license will be issued. **Note** – if you are submitting an amendment with the renewal, call our office prior to submitting the application. The renewal and amendment carry separate fees that will be due.

☐ **Notice that this firm is out of business**. Date: _____

☐ **Not required to license – reason:** _____
Sign & date page 1 and return.

RESPONSIBLE INDIVIDUAL IN CHARGE AT PHYSICAL ADDRESS

A license cannot be issued for manufacturing or holding of foods for distribution in any room used as living or sleeping quarters; or for the manufacturing, assembling, testing, processing, packing, holding or labeling of drugs and/or devices from any personal residence**.**

Please note: Only drug, device, and/or certificate of authority applicants are required to fill in residence address, driver's license number, and date of birth**.**

_____

Name & title Date of birth

_____

Residence address Driver's license number

BUSINESS HOURS OF OPERATION _____ **to** _____

WEBSITE/INTERNET ADDRESS: _____

MAILING ADDRESS INFORMATION (The license and/or courtesy renewal notice will be sent to the address below).

Mailing name: _____

Mailing address: _____

City, State, Zip code: _____

Name of application preparer **(contact person):** _____

Telephone number of contact person**:** _____

Email address of contact person: _____

Fax number for contact person: _____

LICENSE HOLDER INFORMATION: Please enter the 11-digit State Tax Payer's Identification number on file with the Texas Comptroller of Public Accounts. Enter the 9-digit Federal Employee Identification Number **(EIN).**

_____

Taxpayer number **EIN number**

Please note: Only for Drug, Device, and/or Certificate of Authority applications:

Has the applicant, licensee, and/or managing officer(s) been convicted of a felony or misdemeanor? ☐ Yes ☐ No

If yes, please attach a statement explaining the conviction and include a copy of the driver's license with the application.

For the information below, complete the **box** that applies to the ownership of the license. **In addition**, **where stated below, residence address, driver's license number**, **and date of birth are required**.

☐ **Sole Owner / Proprietorship**

Name of sole owner**:** _____

_____

Residence address DLN DOB

☐ **Association** ☐ **State Agency**

Name of Association / State Agency: _____

Address: _____

Contact person: _____

_____

Residence address DLN DOB

Contact person: _____

_____

Residence address DLN DOB

☐ **Partnership** ☐**LP** ☐ **LLP** ☐**LTD**

Name of partnership**:** _____

Address of partnership**:** _____

Effective date of partnership: _____

(partnership information continued on next page)

Partner name:_____

_____

Residence address DLN DOB

Partner name: _____

_____

Residence address DLN DOB

Partner name: _____

_____

Residence address DLN DOB

☐ **Corporation** ☐ **LLC**

Effective date of Incorporation: _____

Corporation Name: _____

Corporation Address:_____

President: _____

_____

Residence address DLN DOB

Officer: _____

_____

Residence address DLN DOB

Officer: _____

_____

Residence address DLN DOB

Registered Agent: _____

_____

Residence address DLN DOB

BE SURE TO COMPLETE ALL 7 PAGES OF THIS FORM

ATTACHMENT A

APPLICANT QUALIFICATIONS

To qualify for the issuance or renewal of a license as a wholesale distributor and/or manufacturer of prescription drugs under these sections, the designated representative of an applicant or license holder must:

(1) Be at least 21 years of age.
(2) Have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs.
(3) Be employed by the applicant full-time in a managerial-level position.
(4) Be actively involved in and aware of the actual daily operation of the wholesale distributor.
(5) Be physically **present at the applicant's place of business during regular business hours**, except when the absence of the designated representative is authorized, including sick leave and vacation leave.
(6) Serve as a designated representative for only one applicant at any one time.
(7) Not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances.
(8) Not have been convicted of a felony under a federal, state, or local law.

I, _____, in my official capacity as the designated representative of the applicant or license holder, do hereby attest I meet all of the qualifications above.

_____
Signature of Designated Representative

Given and signed in the City of _____, State of _____, this _____ day of

_____, 20_____.

The State of _____,

County of _____,

Before me, on this day personally appeared _____, known to me to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that he/she executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this _____ day of _____, A.D., 20 _____.

_____
Notary Public

Please Note:
Failure to provide documents as required may result in a significant delay in licensing or denial of licensure. Each attachment must be completed by a designated representative who is located at the physical address of the business, being licensed. Forms/Attachments MUST be notarized. Attachments A & B must be completed for each designated representative.

For additional information or assistance, please call (512) 834-6727.

ATTACHMENT B

For each person who is a designated representative and/or a manager of each place of business, the applicant shall provide the following information to the department as per 25 TAC Chapter 229.425.

Note: Any information and/or document submitted in response to requirements MUST be signed before a Notary Public.

1. List the person's place(s) of residence for the past seven years:

_____
(Street Address)

_____, _____, _____
(City) (ST) (Zip code)

_____
(Street Address)

_____, _____, _____
(City) (ST) (Zip code)

_____
(Street Address)

_____, _____, _____
(City) (ST) (Zip code)

2. List person's date and place of birth:

_____, ____/_____/_____
(Place) (Date: MM/DD/YYYY)

3. List the person's occupations, positions of employment, and offices held during the past seven years:
(Note: Do NOT Attach Resumes)

_____ _____
(Occupation/Position of Employment) (Office Held)

_____ _____
(Occupation/Position of Employment) (Office Held)

_____ _____
(Occupation/Position of Employment) (Office Held)

4. List the business name and address of any business, corporation, or other organization in which the person held an office as sole proprietor, partner, principal, and/or officer; or in which the person conducted an occupation or held a position of employment:

_____
(Business Name) (Office Held)

_____
(Street Address)

_____, _____ _____
(City) (ST) (Zip Code)

_____
(Business Name) (Office Held)

_____
(Street Address)

_____, _____ _____
(City) (ST) (Zip Code)

5. Provide a statement of whether during the preceding seven years the person was the subject of a proceeding to revoke a license and the nature and disposition of the proceeding:

_____

_____

_____

6. Provide a statement of whether during the preceding seven years the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event:

_____

_____

_____

7. Provide a written description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party:

_____

_____

_____

8. Provide a description of any felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere:

_____

_____

_____

9. Provide a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeals disposition:

_____

_____

_____

Attach a photograph of the person taken not earlier than 30 days before the date the application was submitted. **(Note: Do NOT submit Employee ID, state or government issued identification)**.

I, _____, in my official capacity as the designated
(Print Legibly)
representative of the applicant or license holder, do hereby attest I meet all of the qualifications above.

_____
Signature of Designated Representative / Manager

Given and signed in the State of _____, City of _____,

County of _____, this _____ day of _____, 20__.

Before me, on this day personally appeared _____, known to me
(Print Legibly)
to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that he/she executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this _____ day of _____, A.D.,20 __.

NOTARY SEAL

_____
Notary Public

Please Note:
Failure to provide documents as required may result in a significant delay in licensing or denial of licensure. Each attachment must be completed by a designated representative who is located at the physical address of the business, being licensed. Forms/Attachments MUST be notarized. Attachments A & B must be completed for <u>each</u> designated representative.

For additional information or assistance, please call (512) 834-6727.