



**BUSINESS FILING AND VERIFICATION SECTION  
IN-STATE MANUFACTURE OF  
PRESCRIPTION DRUGS**

**DRUG MFG-  
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, RLU,  
Food & Drug Licensing,  
P.O. Box 12008, Austin, Texas 78711  
For assistance in completing this application call  
(512) 834-6727

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

If you are a manufacturer of non-prescription drugs only, contact this office at (512) 834-6727 for the correct application.

Name Business is Conducted Under (DBA): \_\_\_\_\_

Physical Address to be Licensed: \_\_\_\_\_

City, County, State, Zip Code: \_\_\_\_\_

Telephone # at address: \_\_\_\_\_ ( ) \_\_\_\_\_

**Manufacturer of Medical Gas Only, Please Check:**       YES       NO

**Type of Operation:** (Check all that apply)       Manufacturer       Contract Manufacturer  
 Medical Gas Transfiller – Liquid Oxygen       Medical Gas Transfiller – Compressed  
 Medical Gas Transfiller – Air Liquefaction       Repackager and/or Relabeler  
 Charitable Drug Donor       Outsourcing Facility

**Type of Drugs:** (Check all that apply)  
 Prescription       Nonprescription       Bulk Active Pharmaceutical Ingredient  
 Veterinary       Biologics       Controlled Substance (DEA# \_\_\_\_\_)

**FEE SCHEDULE FOR IN-STATE MANUFACTURERS OF PRESCRIPTION DRUGS**  
 The fee is based on **gross annual sales** for **ALL** drugs manufactured at the licensed place of business. This includes a person who manufactures, prepares, propagates, compounds, processes, packages, or repackages prescription drugs or a person who changes the container, wrapper or labeling of any prescription drug package, and any type of medical gas transfillers.

GROSS ANNUAL DRUG SALES		FEE FOR INITIAL/RENEWAL LICENSE OR CHANGE OF OWNERSHIP	
<input type="checkbox"/> LV1 \$	0.00 - \$ 199,999.99	=	\$1,080.00 per facility
<input type="checkbox"/> LV2 \$	200,000.00 - \$19,999,999.99	=	\$1,755.00 per facility
<input type="checkbox"/> 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.

**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), to a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

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

**ANY RETURNED CHECKS RECEIVED AFTER EXPIRATION DATE WILL BE ASSESSED THE \$100.00 LATE FEE.**

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

**(Medical Gas ONLY Distributors are not required to complete attachment A & B)**

- A list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs. If applicant or firm is not licensed with other states please check here:
- Completed Attachment A.
- Required additional information as listed on Attachment B.

**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.

<b>Print Name:</b>	<b>Title:</b> <input type="checkbox"/> Owner <input type="checkbox"/> President <input type="checkbox"/> Partner <input type="checkbox"/> Corporate Designee / Agent
<b>sign here</b> ►	<b>Date:</b>

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. (Reference: Government Code, Section 552.021, 552.023 and 559.004).

**ALL SIX PAGES OF THE APPLICATION FORM MUST 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 **correspondence only** to:  
Texas Department of State Health Services  
RLU, 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** (including legal entity):

**If change affects multiple licensed locations, contact us at 512-834-6727.**

Change of ownership (including legal entity) requires submission of a new application and fee as listed on page 1.

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.** Any minor amendment including change of DBA name or change in the location of a licensed place of business requires submission of an amended application and fee as listed on page 1 of the amended application. The current expiration date remains in effect.

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.

**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 \_\_\_\_\_.

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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:

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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:

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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:

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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:

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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:

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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  
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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

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