



**DRUG MFG - RX**

**REGULATORY LICENSING UNIT  
IN-STATE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS WHO ARE  
MANUFACTURERS LICENSE APPLICATION**

BUDGET: ZZ114  
FUND: 183

**(Health and Safety Code, Chapter 431)**

LICENSE #:

Return both the completed application and non-refundable fee made payable to the  
TEXAS DEPARTMENT OF STATE HEALTH SERVICES in the envelope provided or mail to:  
Texas Department of State Health Services, PO Box 12008, Austin, Texas 78711.

You may visit our website at: [www.dshs.state.tx.us](http://www.dshs.state.tx.us)

If you are a manufacturer of non-prescription drugs only, contact this office at (512) 834-6626 for the correct application.

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

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

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

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

**Type of Operation:** (Check all that apply)  Manufacturer  Contract Manufacturer  Repackager and/or Relabeler  
 Medical Gas Transfiller – Liquid Oxygen  Medical Gas Transfiller – Compressed  Medical Gas Transfiller – Air Liquifaction

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

**FEE SCHEDULE FOR IN-STATE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS  
WHO ARE MANUFACTURERS**

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 drug 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 MINOR AMENDMENT**

<input type="checkbox"/>	\$ 0.00 - \$ 199,999.99 =	\$ 540.00 for each establishment
<input type="checkbox"/>	\$ 200,000.00 - \$19,999,999.99 =	\$ 877.00 for each establishment
<input type="checkbox"/>	\$20,000,000.00 - \$ or more =	\$1,147.00 for each establishment

**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:**

- 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.

Signature \_\_\_\_\_

- OWNER
- PARTNER
- PRESIDENT
- CORPORATE DESIGNEE / AGENT

Date \_\_\_\_\_

Printed Name & Title \_\_\_\_\_

**PURPOSE OF THIS APPLICATION:** Mark appropriate box to indicate purpose of application, and/or any change in status of firm.

**New** - Start Date of Regulated Activity: \_\_\_\_\_

**Change of Ownership (Including legal entity)** [previous owner: \_\_\_\_\_ Effective Date: \_\_\_\_\_]  
Change of ownership (including change of legal entity) requires submission of a new application and fee as listed on Page 1. The effective date of change becomes the new anniversary date.

**Amended** -  Change of Location [previous location: \_\_\_\_\_] } Enter the date the change  
 Change of Name [previous name: \_\_\_\_\_] } was effective  
 Other: \_\_\_\_\_ Date: \_\_\_\_\_

Any minor amendment including change of name or change in the location of a licensed place of business, requires submission of a new application and fee as listed on Page 1. The current expiration date remains in effect.

**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 or permit will be issued.**

**Notice that firm is out of business.** Date: \_\_\_\_\_  
Sign and date. Return for deletion from our records.

**Not required to license/permit**  
Reason: \_\_\_\_\_

**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.

*\*Residence address, driver's license number, and date of birth are only required of drug, device, and/or certificate of authority applicants*

\_\_\_\_\_  
Name & Title \*Residence Address \*Driver's License Number \*Date of Birth

**BUSINESS HOURS OF OPERATION:** \_\_\_\_\_ m. to \_\_\_\_\_ m.

**WEBSITE/ INTERNET ADDRESS:** <http://www.>\_\_\_\_\_

**BILLING INFORMATION** (The license and/or courtesy renewal notice will be sent to the following):

Billing Name: \_\_\_\_\_

Billing Address: \_\_\_\_\_

City, State, Zipcode: \_\_\_\_\_

Name of Application Preparer (Contact Person): \_\_\_\_\_

Telephone Number of Application Preparer (Contact Person): \_\_\_\_\_

Fax Number of Application Preparer (Contact Person): \_\_\_\_\_

E-mail Address of Application Preparer: \_\_\_\_\_

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. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 522.021, 522.023 and 559.004)

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

For assistance in completing this application, call (512) 834-6626.

Please address any correspondence to: Texas Department of State Health Services, Regulatory Licensing Unit, Food and Drug Licensing Group, 1100 West 49<sup>th</sup> Street, Austin, Texas 78756.

**BE CERTAIN TO COMPLETE ALL PAGES OF THIS FORM  
PAGE 2 OF 3**

**LICENSE HOLDER INFORMATION:** Complete the required ownership information.

Legal name of company must be identical to the name on your State Tax Payer's Identification on file with the Texas Comptroller of Public Accounts.

Legal Name \_\_\_\_\_ Tax Payer ID # or Charter # \_\_\_\_\_ Outlet # \_\_\_\_\_

Mailing Address of Licensed Establishment \_\_\_\_\_ City and State \_\_\_\_\_ Zip \_\_\_\_\_

\* 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.)

*\*Residence address, driver's license number, and date of birth are only required of drug, device, and/or certificate of authority applicants*  
**INCLUDE A COPY OF YOUR DRIVER'S LICENSE**

**SOLE OWNER / PROPRIETORSHIP**

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

**PARTNERSHIP**       **LP**       **LLP**       **LTD**

Name of Partnership \_\_\_\_\_ Effective Date of Partnership \_\_\_\_\_

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

**ASSOCIATION**

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

**CORPORATION**       **LLC**

Name of Corporation \_\_\_\_\_ Date and Place of Incorporation \_\_\_\_\_

President's Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Officer's Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Officer's Name \_\_\_\_\_ \*Residence Address \_\_\_\_\_ \*Drivers License Number \_\_\_\_\_ \*Date of Birth \_\_\_\_\_

Name of Registered Agent \_\_\_\_\_ \*Residence Address \_\_\_\_\_ Telephone Number \_\_\_\_\_

**ATTACHMENT A**  
**APPLICANT QUALIFICATIONS**

To qualify for the issuance or renewal of a license as a wholesale distributor/ 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; and
- (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

This form must be completed and submitted for **each** designated representative. For additional information or assistance, please call (512) 834-6626.

## ATTACHMENT B

**(1) 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. The information submitted below must be signed before a Notary Public.**

(A) the person's place(s) of residence for the past seven years;

(B) the person's date and place of birth;

(C) the person's occupations, positions of employment, and offices held during the past seven years;

(D) 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;

(E) 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;

(F) 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;

(G) 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;

(H) 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;

(I) 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 appeal's disposition; and

(J) a photograph of the person taken not earlier than 30 days before the date the application was submitted.

For additional information or assistance, please call (512) 834-6626.