



**REGULATORY LICENSING UNIT  
IN-STATE MANUFACTURERS 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 fee 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 Under Which Business is Conducted (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 Liquification     Repackager and/or Relabeler  
 Charitable Drug Donor

**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 for each establishment
<input type="checkbox"/> LV2 \$ 200,000.00 - \$19,999,999.99 =	\$1,755.00 for each establishment
<input type="checkbox"/> LV3 \$20,000,000.00 - \$ or more =	\$2,295.00 for each establishment

**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>
------------------	--------------





**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.**

**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 appeal's disposition:

---

---

---

10. 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 representative of the  
(Print Legibly)  
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 to be the person  
(Print Legibly)  
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

NOTARY SEAL

**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.