



**REGULATORY LICENSING UNIT
IN-STATE MANUFACTURERS OF PRESCRIPTION DRUGS**

**DRUG MFG-RX
2501**

Minor Amendment 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 Liquifaction 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 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"/> LV1 \$ 0.00 - \$ 199,999.99 =	\$ 540.00 for each establishment
<input type="checkbox"/> LV2 \$ 200,000.00 - \$19,999,999.99 =	\$ 877.00 for each establishment
<input type="checkbox"/> LV3 \$20,000,000.00 - \$ or more =	\$1,147.00 for each establishment

- | | |
|--|-----------------------------------|
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| <input type="checkbox"/> LV2 \$ 200,000.00 - \$19,999,999.99 = | \$ 877.00 for each establishment |
| <input type="checkbox"/> LV3 \$20,000,000.00 - \$ or more = | \$1,147.00 for each establishment |

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.

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

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

- New** - Start Date of Regulated Activity: _____
- Change of Ownership or Change of Legal Entity:** requires submission of an initial application and fee as listed on Page 1.

PLEASE NOTE: If change affects multiple licensed locations contact us at 512-834-6727 prior to submitting application.

- Previous owner name _____
- Previous legal entity name: _____
- Effective Date of Change: _____

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

Any minor amendment including change of name or change in the location of a licensed place of business requires submission of a minor amendment application and fee as listed on page 1 of that application. 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 out of business: _____ **Not required to license/permit**
Sign and date 1st page and return original license for deletion from our records. 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.

***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 *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. You may visit our website listed below for more information on the 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.

Visit our website at: www.dshs.state.tx.us

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

LICENSE HOLDER INFORMATION: Please enter the 11 digit State Tax Payer's Identification number or Federal Identification number.

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****Please Note: For ONLY 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.)

* Please include a copy of Driver's License with application.

* Applicants are required to fill in residence address, driver's license number, and date of birth below.

SOLE OWNER / PROPRIETORSHIP

Name of Sole Owner: _____
Residence Address DLN DOB

Partnership LP LLP LTD Effective Date of Partnership _____

Name of Partnership: _____

Partnership Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

*** Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:**

Partner Name: _____
Residence Address DLN DOB

Partner Name: _____
Residence Address DLN DOB

Partner Name: _____
Residence Address DLN DOB

Association **State Agency**

Name of Association / State Agency: _____

Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

*** Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:**

Name: _____
Residence Address DLN DOB

Name: _____
Residence Address DLN DOB

Corporation **LLC**

Date and Place of Incorporation: _____

Corporation Name: _____

Corporation Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

***Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:**

President Name: _____
Residence Address DLN DOB

Officer's Name: _____
Residence Address DLN DOB

Officer's Name: _____
Residence Address DLN DOB

Name of Registered Agent: _____
Residence Address DLN DOB

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)

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

(Street Address)

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

(Street Address)

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

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)

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

(Business Name) (Office Held)

(Street Address)

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

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.