BUSINESS FILING AND VERIFICATION SECTION
IN-STATE MANUFACTURERS OF
PRESCRIPTION DRUGS

Minor Amendment 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

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: _____________________________

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 □ Outsourcing Facility

Type of Drugs: (Check all that apply)
□ Prescription □ Bulk Active Pharmaceutical Ingredient
□ Biologics □ Nonprescription □ Veterinary □ Controlled Substance
□ or more = (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.

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<tr>
<th>GROSS ANNUAL DRUG SALES</th>
<th>FEE FOR MINOR AMENDMENT</th>
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<tbody>
<tr>
<td>□ LV1 $ 0.00 - $ - 199,999.99 =</td>
<td>$ 540.00 per facility</td>
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<tr>
<td>□ LV2 $ 200,000.00 - $ - 1,999,999.99 =</td>
<td>$ 697.00 per facility</td>
</tr>
<tr>
<td>□ LV3 $ 2,000,000.00 - $ - 9,999,999.99 =</td>
<td>$ 847.00 per facility</td>
</tr>
<tr>
<td>□ LV4 $ 10,000,000.00 - $ - 19,999,999.99 =</td>
<td>$ 997.00 per facility</td>
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<tr>
<td>□ LV5 $ 20,000,000.00 - $ - or more =</td>
<td>$ 1,147.00 per facility</td>
</tr>
</tbody>
</table>

BE SURE TO COMPLETE ALL PAGES OF THIS FORM
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.

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: □ Owner □ President □ Partner □ 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 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
Food and Drug Licensing Group, MC 2835
PO Box 149347
Austin, Texas 78714-9347

PAGE 2 OF 6
PURPOSE OF THIS APPLICATION: Mark appropriate box to indicate purpose of application, and/or any changes in status of firm.

☐ For a change in the Designated Representative only. For this change, please submit this page and the attached A&B documents only. No other documents are required.
License Number: __________________

☐ Amendment of ownership name (this does not include an ownership change): This means the EIN/Taxpayer Numbers are remaining the same and the firm has submitted an amendment with the Secretary of State and the Comptroller’s office. The current expire date remains in effect.
If change affects multiple licensed locations, contact us at 512-834-6727.

Previous name: _____________________________

License number: __________________ Effective date of change: __________________

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

☐ Location change (previous location): ______________________________________

☐ DBA Name Change (previous):______________________________________________

☐ 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)
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<tr>
<th>Partner name:</th>
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<td>Residence address</td>
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| □ Corporation   □ LLC |

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<th>Effective date of Incorporation:</th>
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<tr>
<th>Corporation Name:</th>
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<th>Corporation Address:</th>
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<th>President:</th>
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<td>Residence address</td>
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<th>Officer:</th>
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<th>Registered Agent:</th>
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<td>Residence address</td>
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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 ______________________________,

PAGE 1 OF 2
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)

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<th>Occupation/Position of Employment</th>
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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:

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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 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 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

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