

# REGULATORY LICENSING UNIT OUT-OF-STATE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS LICENSE APPLICATION

(Health and Safety Code, Chapter 431)

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/bfds

#### DRUG OOS – RX

BUDGET:	ZZ114
FUND:	183
LICENSE #:	

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)				
□ Wholesale Distributor □ Medical Gas Distributor □ Own label distributor □ Broker □ Other				
Type of Drugs: (Check all that apply)       □ Prescription       □ Nonprescription       □ Bulk Active Pharmaceutical Ingredient         □ Veterinary       □ Biologics       □ Controlled Substance (DEA#)				
FEE SCHEDULE FOR OUT-OF-STATE WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS INITIAL/RENEWAL LICENSE OR CHANGE OF OWNERSHIP  The fee is based on all gross annual sales of prescription drugs delivered into Texas.				
$ \Box \$ 0.00 - \$19,999,999.00 = \$1,350.00  \Box \$20,000,000.00 - \$ or more = \$2,025.00 $				
☐ 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.				
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.				
ADDITIONAL DOCUMENTATION REQUIRED: (Medical Gas ONLY Distributors are not required to complete attachment A & B)				
A current copy of your home state's license OR a completed "Drug Distributor License Verification Affidavit" from the resident state licensing authority.				
<ul> <li>□ Completed Attachment A.</li> <li>□ Required additional information as listed on Attachment B.</li> </ul>				
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 □ Date □ PRESIDENT □ CORPORATE DESIGNEE / AGENT				

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:]					
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 exp date will result in a delinquency fee for each location and must be remitted before the license or will be issued.					
□ Notice that firm is out of business. Date: □ Not required to license/permit 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. tom.					
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 <a href="http://www.dshs.state.tx.us">http://www.dshs.state.tx.us</a> for more information on Privacy Notification. (Reference: Government Code, Section 522.021, 522.023 and 559.004)

### ALL THREE PAGES OF THE APPLICATION FORM <u>MUST</u> 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.

LICENSE HOLDER INFORMATION: Complete the required ownership information.							
Legal name of company must b Accounts.	e identical to the name on your	r State Tax Payer's Ide	entification on file with the Tex	as Comptro	ller of Public		
Legal Name		Tax Payer ID # or Charter #		Outlet#			
Mailing Address of Licensed Establishme	ent Cit	y and State		Zip			
* Has the applicant, licensee, and/or managing officer(s) been convicted of a felony or misdemeanor?  (If yes, please attach a statement explaining the conviction.)			□Yes	□No			
*Residence address, driver's lic	ense number, and date of birth <u>INCLUDE A</u> CO	n are only required of PY OF YOUR DRI	drug, device, and/or certificate VER'S LICENSE	of authority	applicants		
□ SOLE OWNER / PROPI	RIETORSHIP						
Name	*Residence Address		*Drivers License Number		*Date of Birth		
□ PARTNERSHIP	$\Box$ 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							
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	*R	esidence Address		Telephor	ne Number		

Revised 02/01/06

## 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 qualifi	cations 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 appearedsubscribed to the foregoing instrument and acknowledge expressed.						
Given under my hand and seal of office this day	y of	, A.D.,20				
Notary Public	_					

This form must be completed and submitted for <u>each</u> 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.