

Applicant Name: _____

9904/001	Application	\$ 525
9904/006	Regulatory fee	\$ 10
9904/001	Controlled Substance	\$ 40
9904/001	Sterile Compounding	\$ 250



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
BOARD OF PHARMACY
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243
PHONE: (615) 741-2718 FAX: (615) 741-2722
<http://health.state.tn.us/boards/pharmacy/>

BUSINESS APPLICATION AND INSTRUCTIONS FOR MANUFACTURER/WHOLESALE/DISTRIBUTOR LICENSE

Pursuant to Rule 1140-09-.01(1): Every manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter. **(2):** An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.

NOTE: A new application must be submitted to the Tennessee Board of Pharmacy, along with the required application fee(s), anytime there is a Name, Location, or Ownership change.

Pursuant to Public Chapter 430, signed into law by Governor Haslam on May 16, 2013, all Tennessee-licensed manufacturers, wholesalers and distributors of controlled substances, including tramadol, must regularly submit a report in Automation of Reports and Consolidated Order System *(ARCOS) format to the Board of Pharmacy of all CII-CV controlled substance distributions to a Tennessee licensee.

***For instructions regarding data submission for Tennessee-Licensed Manufacturers, Wholesalers and Distributors, please visit: <http://health.tn.gov/apps/ARCOS/>.**

APPLICATION INSTRUCTIONS

AND

CHECKLIST

For your convenience, the checklist below outlines the required documents to be submitted with all applications for consideration for issuance of a license:

Check or money order made payable to the Tennessee Board of Pharmacy

*Registration Fee	\$525.00
*State Regulatory Fee	\$10.00
**Controlled Substance Fee	\$40.00
***Sterile Compounding Fee	\$250.00

***Required**

NOTE: Please see the rules below to determine if the facility is required to also register for controlled substances and/or sterile compounding.

****Pursuant to Rule 1140-01-.11:** No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board.

***** Pursuant to Rule 1140-01-.12 (1):** No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

Instructions cont'd on next page...

- List of owners, partners, board of directors, or corporate officers**
- Completed criminal background check – Instructions for completing a background check may be obtained here: <http://health.tn.gov/CBC/>.**

Pursuant to Rule 1140-09-.02(1)(e)(6): The results of a criminal background Check for the owner or manager of the facility seeking licensure, must be submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy’s licensure application materials.

NOTE: When registering for fingerprinting, please include the name of the business entity (see below).

Applicant Information

Instructions
Items marked with an * are required. A red exclamation mark will appear to the right of any field that has an error. Click on the exclamation mark for a description of the error.

Applicant Name

Prefix <input type="text"/>	First Name * <input type="text" value="First (COMPANY NAME)"/>	Middle Name <input type="text"/>	Last Name * <input type="text" value="Last"/>	Suffix <input type="text"/>
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IN ADDITION TO THE ITEM(S) ABOVE, ALL **NON-RESIDENT** APPLICATIONS MUST ALSO BE ACCOMPANIED BY THE FOLLOWING:

- Copy of the license issued by the state which the facility is located**
- Copy of the inspection report completed within the last 12 months or a statement from the resident state licensing agency explaining its inspection policy**
- Copy of DEA registration certificate (if applicable)**

NOTE: If the applicant utilizes a Third Party Logistics Provider (3PL) for manufacture, sale, or distribution of its product(s), the application must be completed to reflect the 3PL business name and address under the section for “Facility Address”. The business name and address on all supporting documents must correspond with the information provided on the application.

UNDERSTANDING THE LICENSURE PROCESS

It is the Board's policy that all applications still not approved after one (1) year will expire. If you wish to reapply for licensure, you will be required to submit a new application with registration fee.

- All application fees are **NON-REFUNDABLE**.
- Please send all required documents and fees to:

**Office of Health Related Boards
Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, TN 37243
*(Courier services use 37228)***

- **Please allow ten (10) business days** for information mailed to the board's office to be received. Special courier services will not appreciably reduce the time it takes to process an application. **It takes approximately eight (8) weeks for a license to be issued.**
- Upon receipt of the application, an administrative member of the Board of Pharmacy will conduct a preliminary review of the application. If additional information is required, notification will be provided via regular mail or electronic mail.
- Applications for a **resident** facility will be forwarded to a Board of Pharmacy investigator for an inspection. Upon receipt of a satisfactory inspection report, the application will undergo a final review and a license will be issued.
- Upon receipt of all required documents, applications for a **non-resident** facility will undergo a final review and a license will be issued.
- Once an application has been approved, **please allow 7-14 business days for receipt of the license certificate.**

Please limit phone calls and/or emails to the board office regarding the status of an application. You may verify the license status here: http://health.state.tn.us/HCF/Facilities_Listings/facilities.htm

County: _____

Tennessee License No. _____

APPLICATION FOR:

- New License
- Name Change
- Location Change
- Ownership Change

TYPE OF LICENSE

APPLYING FOR:

- Manufacturer
- Wholesaler
- Distributor
- Outsourcing Facilities
- Oxygen Supplier

TYPE OF OPERATION:

- Manufacturer
- Wholesaler
- Distributor
- Repackager
- Oxygen
- Other: _____

CORPORATE MAILING ADDRESS:

Company Name		
Address Line 1		
Address Line 2		
City	State	Zip Code
Corporate Contact Person		Corporate Telephone

FACILITY ADDRESS:

Company Name		
Address Line 1		
Address Line 2		
City	State	Zip Code
Manager at Facility		Telephone Number

Please complete if applying for a Name, Location, or Ownership change:

Previous Company Name		
Previous Address Line 1		
Previous Address Line 2		
City	State	Zip Code

CONTROLLED SUBSTANCES: Yes No **DEA Number:** _____

STERILE COMPOUNDING: Yes No

SELL/DISTRIBUTE DRUGS OR DEVICES TO:

- Wholesalers Distributors Community Pharmacies Hospital Pharmacies
- Long-Term Care Facilities Veterinarians Researchers Prescribing Practitioners
- Other: _____

CORPORATIONS: Must attach a list of your Board of Directors with the address of the corporation. If not a corporation, please provide a list of owner(s), partner(s), or officer(s), including addresses and phone numbers.

TYPE OF OWNERSHIP:

- Sole Proprietorship
- Partnership
- Corporation
- LLC
- Other: _____

DIRECTOR/OFFICER NAME & TITLE:

TO BE COMPLETED BY: (Check one) **OWNER** **OFFICER OF CORP.** **ADMINISTRATOR**

Are there any charges involving moral turpitude or violation of pharmacy, or any other laws pending against you?
 Yes **No** (If yes, please explain or attach pertinent documents) _____

I do solemnly swear and affirm that I understand the pharmacy laws of Tennessee and that the information in this application is true and correct to the best of my knowledge. I further attest that this business will comply with all the provisions of the Tennessee Pharmacy Law and Regulations.

Signature _____

NOTARY PUBLIC: I attest that the above signature (s) of _____	
sworn to and subscribed to before me this _____ day of _____, _____	
My commission expires _____	Notary Signature _____

AFFIX SEAL HERE

Note: Every business licensed by the Tennessee Board of Pharmacy must possess a copy of the board publication which contains Pharmacy Law and Regulations; the Tennessee Drug Control Act; and the Tennessee Food, Drug & Cosmetic Act (applicable parts only).

Does the facility possess a printed or electronic version of the TN Law Book? **Yes** **No**

FOR BOARD USE ONLY:	
FILE #: _____	EXACT #: _____
LICENSE #: _____	LICENSURE DATE: _____



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
OFFICE OF HEALTH RELATED BOARDS
BOARD OF PHARMACY
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243
<http://health.state.tn.us/Boards/Pharmacy>

**TENNESSEE BOARD OF PHARMACY
MANUFACTURER, OUTSOURCING FACILITY, OXYGEN SUPPLIER AND
WHOLESALE/DISTRIBUTOR COMPLIANCE SURVEY**

To ensure regulatory compliance and promote product safety, the Tennessee Board of Pharmacy is surveying all entities seeking licensure in Tennessee as a Manufacturer, outsourcing facility, oxygen supplier and Wholesaler, or a Distributor. Please answer the questions below and return to the Board office. You may respond by mail to Tennessee Board of Pharmacy 665 Mainstream Drive, Nashville, TN 37243; by fax to 615-741-2722; or by scanning and e-mailing to: Sheila.bush@tn.gov.

Pursuant to Tennessee Code Annotated (T.C.A.) §63-10-305 (8), the request to complete and return this survey is considered a lawful order of the Board of Pharmacy. Response is required before a license will be issued. Please retain a copy of your response at the firm's location.

NAME OF FACILITY: _____

ADDRESS OF FACILITY: _____

CITY, STATE, ZIP: _____

PHONE NUMBER: _____

NAME OF PERSON RESPONSIBLE FOR RESPONDING: _____

PART 1: MANUFACTURER

T.C.A. §63-10-204 (21) "Manufacturer" means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

1. By this definition, is this firm a “manufacturer”? Yes No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition:

If “yes”, please answer the following questions:

2. Is the firm licensed or registered with FDA? Yes No

If “no”, please provide a brief explanation why:

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products has the firm manufactured in the past 12 months? _____

Please attach a list of all products manufactured at the facility in the past 12 months along with the volume produced of each item.

4. Are any sterile products manufactured? Yes No

If “yes”, please attach a list of all sterile products manufactured and the volume produced of each item.

5. Does the firm ship product into other states? Yes No

If “yes”, please attach a list of all other states into which shipment occurs.

6. Is the firm licensed in all states listed in Question 5? Yes No

If “yes”, please attach proof of licensure.

If “no”, please describe why not:

PART 2: WHOLESALER

T.C.A. §63-10-204 (43) *“Wholesaler” means a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.*

1. By this definition, is this firm a wholesaler? _____Yes _____No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition:

If “yes”, please answer the following questions:

2. Is the firm licensed or registered with FDA? _____Yes _____No

If “no”, please provide a brief explanation why:

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products has the firm wholesaled in the past 12 months? _____

4. Are any sterile products wholesaled? _____Yes _____No

5. Does the firm ship products into other states? _____Yes _____No

If “yes”, please attach a list of all other states into which products are shipped.

6. Is the firm licensed by all other states into which it ships? _____Yes _____No

If “yes”, please attach proof of licensure.

If “no”, please describe why not:

PART 3: DISTRIBUTOR

T.C.A. § 63-10-204 (13) *“Distribute” means the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient’s agent;*

1. By this definition, does this firm “distribute” legend drugs or devices? _____Yes _____No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition:

If “yes”, please answer the following questions:

2. Is the firm licensed or registered with FDA? _____Yes _____No

If “no”, please provide a brief explanation why not:

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products does the firm distribute? _____

4. Are any sterile products distributed? _____Yes _____No

5. Does the firm ship product into other states? _____Yes _____No

If “yes”, please attach a list of all other states into which products are distributed.

6. Is the firm licensed by all other states into which the firm ships? _____Yes _____No

If “yes” please attach proof of licensure.

If “no”, please describe why not:

Part 4: OUTSOURCING FACILITY

T. C.A. §63-10-204 *“Outsourcing facility” means a facility engaged in the compounding of sterile drugs which has elected to register as an outsourcing facility with the U. S Food and Drug Administration and which complies with all relevant federal laws and regulations.*

2. By this definition, does this firm “distribute” legend drugs or devices? _____Yes _____No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition:

If “yes”, please answer the following questions:

2. Is the firm licensed or registered with FDA? _____Yes _____No

If “no”, please provide a brief explanation why not:

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products does the firm distribute? _____

4. Are any sterile products distributed? _____Yes _____No

5. Does the firm ship product into other states? _____Yes _____No

If “yes”, please attach a list of all other states into which products are distributed.

6. Is the firm licensed by all other states into which the firm ships? _____Yes _____No

If “yes” please attach proof of licensure.

If “no”, please describe why not:

Part 5: OXYGEN SUPPLIER

T. C.A. §63-10-204 *“Oxygen Supplier” means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug and Cosmetic Act to any person residing in this state.*

3. By this definition, does this firm “distribute” legend drugs or devices? _____Yes _____No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition:

If “yes”, please answer the following questions:

2. Is the firm licensed or registered with FDA? _____Yes _____No

If “no”, please provide a brief explanation why not:

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products does the firm distribute? _____

4. Are any sterile products distributed? _____Yes _____No

5. Does the firm ship product into other states? _____Yes _____No

If “yes”, please attach a list of all other states into which products are distributed.

6. Is the firm licensed by all other states into which the firm ships? _____Yes _____No

If “yes” please attach proof of licensure.

If “no”, please describe why not:

Tennessee License No. _____

END OF SURVEY.