Applicant Name: _____

9904/001	Application	$ 525
9904/006	Regulatory fee	$ 10
9904/001	Controlled Substance	$ 40

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://tn.gov/health/article/pharmacy

BUSINESS APPLICATION AND INSTRUCTIONS FOR THIRD-PARTY LOGISTICS PROVIDER (3PL)

Pursuant to Rule 1140-16-.02(1): Before any 3PL provides or coordinates warehousing or other logistics services within this state for a prescription drug and/or prescription device on behalf of a manufacturer, wholesale distributor or dispenser the 3PL shall be licensed by the Board in accordance with this Chapter whether physically located within this state or outside the state. Where operations are conducted at more than one location, each such location shall be licensed by the Board. A warehouse provided by a 3PL shall be inspected by the Board's inspector (s) or inspectors of the state where the warehouse is physically located prior to providing services **(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.

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**

*__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.

ALL APPLICANTS

☐ The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant who can be reached at any time by the Board, the Department of Health or any agents thereof.

☐ All trade or business names used by the 3PL (including "is doing business as: and "formerly known as"), full business address, and telephone number.

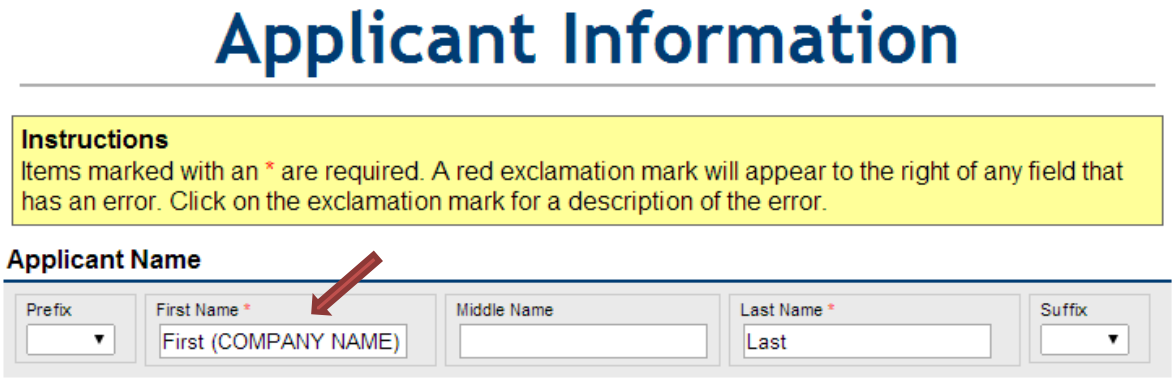
☐ Addresses, telephone numbers and names of contact persons for all facilities used by the 3PL for storage, handling, and distribution.

☐ A list of all state and federal licenses, registrations or permits including the number of each such license, registration, or permit issued to the 3PL.

☐ Copy of the Drug Enforcement Administration (DEA) registration if applicable.

Pursuant to Rule 1140-16-.03(1)(f)6: The results of a Criminal Background Check for the owner or manager of the 3PL seeking licensure, must be submitted directly to the Board by the vendor identified in the Board's licensure application materials. **Instructions for completing a background check may be obtained here:** https://www.tn.gov/health/health-professionals/criminal-background-check/cbc-instructions.html

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



IN ADDITION TO THE ITEM(S) ABOVE, ALL **NON-RESIDENT** APPLICATIONS MUST ALSO BE ACCOMPANIED BY THE FOLLOWING:

- ☐ Copy of the manufacturer, wholesaler, or distributor license issued by the state which the facility is physically located.
- ☐ Copy of a Verified-Accredited Wholesale Distributors accreditation for the National Association Boards of Pharmacy (NABP).
- ☐ Copy of DEA registration certificate (if applicable).

NOTE: Pursuant to Board rule 1140-16-.02 (2) (4) Each manufacturer, wholesaler, distributor that ships prescription drugs and/or prescription devices into or from the State of Tennessee shall be licensed by the Board accordingly;

Board rule 1140-16-.02(2)(5) Each wholesaler distributor who is also engage in providing 3PL services, as defined in Tenn. Code. Ann § 63-10-204 (6) shall obtain a license to operate as a wholesale distributor issued by the Board and shall obtain a separate license to operate as a 3PL issued by the Board

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: https://apps.health.tn.gov/Facilities_Listings/facilities.htm

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APPLICATION FOR: ☐ New License ☐ Name Change ☐ Location Change ☐ Ownership Change

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:** _____

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) _____

_____

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

AFFIDAVIT AND RELEASE

I, _____, of _____
(Applicant's Name) *(City)* *(State)*
affirm that I am the owner, manager and/or administrative staff for this manufacturer listed in this application.

I affirm that I am the owner, manager and/or administrative staff and accountable to the Board of Pharmacy for this practice site's compliance with all state statutes and regulations governing the practice of being a licensed manufacturer in Tennessee.

I affirm that before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, that this practice site must be licensed by the Tennessee Board of Pharmacy

THIS CERTIFIES THAT THE INFORMATION SUBMITTED BY ME IN THIS APPLICATION IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

_____ _____
SIGNATURE 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
THIRD PARTY LOGISTICS (3PL) 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 Third Party Logistic Provider. 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: Pharmacy.Health@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: _____

THIRD PARTY LOGISITICS PROVIDER (3PL)

Board rule 1140-01-.01 (42) *"Third party logistics provider (3PL)" means a person who provides or coordinates warehousing or other logistics services of a drug or device on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device, but does not take ownership of the drug or device, or has responsibility to direct the sale or disposition of the drug or device.*

1. By this definition, is this firm a "third party logistics provider (3PL)"? ☐ 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:

_____

_____

_____

_____