



STATE OF TENNESSEE  
DEPARTMENT OF HEALTH  
Office of Health Related Boards  
665 Mainstream Drive  
Nashville, TN 37243  
<http://tn.gov/health/topic/pharmacy-board>

TENNESSEE BOARD OF PHARMACY  
MANUFACTURER 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. 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, Tennessee 37243; by fax to 615-741-2722; or by scanning and e-mailing to: [Pharmacy.Health@tn.gov](mailto: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: \_\_\_\_\_

**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:

Are you a virtual manufacturer?  Yes  No

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: \_\_\_\_\_