STATE OF TENNESSEE
DEPARTMENT OF HEALTH
OFFICE OF HEALTH RELATED BOARDS
BOARD OF PHARMACY
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 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, TN 37243; by fax to 615-741-2722; or by scanning and e-mailing to: PharmacyHealth@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: __________________________

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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: __________________________