Wisconsin Department of Safety and Professional Services

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PHARMACY EXAMINING BOARD

DRUG MANUFACTURER SELF-INSPECTION INFORMATIONAL SHEET

The Board no longer requires the Department of Safety and Professional Services to send inspectors to conduct on-site inspections prior to licensure.

In lieu of the above, the Board requires the person responsible for manufacturing to complete the "Drug Manufacturer Self-Inspection Report" (**Form #2599**). Please complete each line indicating compliance, by initialing each item and signing the form. If the facility is in non-compliance with any portions of the report indicate why the facility is in non-compliance and when the facility will be in compliance. Return the entire report to the Board office when completed. Please make a copy for your files.

After the report has been reviewed and is found to be in order, a license number will be issued if all other requirements have been satisfied.

The Department, on behalf of the Board, will conduct an unannounced audit of the facility location within one year after the date the license was issued to verify that the facility is in compliance with the "Drug Manufacturer Self-Inspection Report" (**Form #2599**) as well as the Wisconsin statutes and administrative code relating to the practice of a drug manufacturer.

Notice To Credential Holders Conducting Self-Inspections

The Division of Legal Services and Compliance in the Department of Safety and Professional Services conducts a follow-up inspection to the self-inspection done by manufacturers prior to their opening for business.

Below is a list of the most frequently occurring problems we found during our follow-up inspections. The reference is to the Pharmacy Board rule or statute. This list is being provided to assist new businesses in conducting their self-inspections.

Drug Manufacturer:

- Prescription labels – Not having the correct address of the facility or using the name of the previous owners.
- Recordkeeping - Manufacturers did not have adequate records to document their stock from receipt to disposition (Phar 13.11(4)).
- Alarm systems – All facilities must have a functioning alarm system at all times to detect entry after hours. Some facilities were found to have opened without an alarm system in place or the alarm system was not working at various times (Phar 13.10(4).
- Written policies and procedures-the manufacturer frequently assumes that the state follows the same requirements as the federal government. The federal government is responsible for overseeing the quality of the prescription drugs and/or devices; and how the employer treats their employees. The state's concern is that policies and procedures reflect how the manufacturer handles the security and operation of the facility in relationship to the prescription drugs and/or devices. Numerous policy and procedural manuals were found to be inadequate, especially in covering emergency procedures (Phar 13.15).

Procedure For Reporting Theft or Loss of Controlled Substances

The U.S. Department of Justice, DEA registrants are responsible for reporting any theft or loss of controlled substances to the DEA, Kluczynski Building, Ste. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-1236, or 1-800-478-7642 toll free 24 hours), and to the Pharmacy Examining Board, P.O. Box 8935, Madison, WI 53708-8935, (608-266-2112). Report the theft or loss on DEA Form #106 (Report of Theft or Loss of Controlled Substances), obtainable from DEA at www.deadiversion.usdoj.gov. Make four (4) copies. Send the original and one copy to the DEA office. Send one copy to the Pharmacy Examining Board at the above address and one copy should be kept with the biennial inventory in the pharmacy.

All thefts or losses must also be reported to the local law enforcement officials. Send a copy of the police report, when available to the Pharmacy Examining Board.

Procedure For Destroying Controlled Substances

Contact the United States Department of Justice, 1000 N. Water Street, Room 1010, Milwaukee, WI 53202, or www.deadiversion.usdoj.gov for the proper forms.

Approved Prescription Drug Products And Code Of Federal Regulations

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.

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PHARMACY EXAMINING BOARD

MANUFACTURER SELF-INSPECTION REPORT

Choose Type: ☐ New Location ☐ New Owner ☐ Change in Ownership

Applicant 's Name

DBA Name (name or title under which business is operated)

Application ID Number (if applicable)

Telephone Number ___ - ___ - ____

Address (street, city, state, zip)

Hours: (open - close)	**Mon.-Fri:**	**Sat:**	**Sun:**

Name of Owner or Names and Titles of all Partners or Corporate Officers: (attach additional sheets if necessary)

Name

Name

If the facility is in non-compliance with any portions of the "Drug Manufacturer Self-Inspection Report" please indicate why the facility is in non-compliance and when the facility will be in compliance. Return the entire "Drug Manufacturer Self-Inspection Report" to the Board office when completed. Please make a copy for your files.

Place initials certifying compliance with Wis. Admin. Code § Phar 12.

☐ The establishment is registered with the food and drug administration and complies with all applicable requirements of 21 CFR 200, 201, 202, 207, 210, and 211. **Note: attach copy of the most current food and drug administration inspection.**

☐ If applicable, the establishment is registered with the Drug Enforcement Administration (DEA) and complies with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311, and 1312. **Note: attach copy of the most current DEA inspection.**

☐ A manufacturer license may not be transferred from one establishment to another or from one person to another. Each establishment requires a separate license.

Place initials certifying compliance with Wis. Admin. Code §Phar 12.04.

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AFFIDAVIT

Signature **(Print and Sign Form)** Date __/__/__