

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		03/19/2013 - 03/21/2013
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
TO: Charles A. Lindstrom, Owner		

FIRM NAME	STREET ADDRESS
Nora Apothecary and Alternative Therapies, Inc.	1101 E. 86th Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46240	Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, the firm fails to ensure that each batch of aseptically processed injectable drug products, which it distributes, passes sterility and endotoxin testing before distribution. The last sterility testing was conducted on the product Trimix on July 25, 2008. No endotoxin testing has ever been conducted.

**OBSERVATION 2**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, the firm fails to assure that each batch of aseptically processed injectable drugs it distributes, meets appropriate potency limits before distribution. The last potency testing was conducted on July 25, 2008 on Trimix. For example, Bimix, Trimix and PGE-1 are routinely released with no assay testing prior to distribution.

**OBSERVATION 3**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

- 1) There is no aseptic process validation (media fills) simulating the aseptic processes that take place for producing finished dosage forms.
- 2) The ISO 5 hood in which aseptic procedures are completed was observed to have supplies stored within and above the hood, the supplies on top of the hood are used during aseptic processing.
- 3) The ISO 5 hood is located in an area that is not a classified area.
- 4) The ISO 5 hood has only been certified on an (b) (4) basis (b) (4). There is no dynamic air testing during the certification. There was no evidence of smoke studies ever being conducted to verify the laminar air flow.
- 5) While observing aseptic operations the following deficiencies were noted:

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Larry K. Austin, Investigator Marie A. Fadden, Investigator	03/21/2013

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- a) the operator had exposed skin on his neck and eye area.
- b) the operator's movements were not slow and deliberate within the ISO 5 hood.
- c) the operator initially sprayed the ISO hood surface with (b) (4) and using an ungloved hand wiped the front inside working surface of the ISO 5 hood.
- d) the operator did not wash his hands prior to gowning and donning gloves, which is not in accordance with their written procedure.
- 6) the procedure "Nora Apothecary Pharmacy Policies & Procedures" Effective February 2012 is deficient in that:
  - a) the cleaning procedures do not include the use of sporicidal agents and do not specify to use sterile 70% IPA. Currently, no sporicidal cleaning agent is used. The type of wipes to use in the hood are not specified, regular household paper towels were observed to currently be in use. In addition, the procedure does not describe the gowning of the operator prior to cleaning the hood area.
  - b) The gowning of operators prior to entering the aseptic processing areas is done using non-sterile gowning materials including the outer gown, gloves, hairnet, and shoe covers.
- 7) There is a failure to ever perform (b) (4) on the (b) (4) (oil and solvent based products) and the (b) (4), Inc. (b) (4) (stock solutions and finished dosage forms).
- 8) The "paddles" used to do surface samples, fingertip samples and air samples are incubated for (b) (4) on a shelf in the pharmacy area. They are placed on top of the computer modem, which is on the shelf. The area was observed to be dusty and there is no temperature monitoring in room.
- 9) The pre-filters to the area in which the ISO 5 hood is located has it's own HEPA filter, air flows through a pre-filter prior to the HEPA filter, according to their procedure, this filter is to be changed (b) (4) it has not been changed since December 10, 2012.

**OBSERVATION 4**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Environmental monitoring of the ISO 5 hood does not occur each time an injectable drug is formulated therein. For example, during the processing of Bimix Injectable, prescription number (b) (6) on 3/19/2013, no environmental monitoring was observed. In addition, personnel monitoring of the operator was also not performed on this same day. The last environmental monitoring was done December 10, 2012 and the last personnel monitoring was done September 17, 2012.

**OBSERVATION 5**

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically there is no stability data for any aseptically processed injectable drugs produced by this firm including Bimix (90 day BUD), Trimix (90 day BUD), PGE-1 (90 day BUD), and the stock solutions Papaverine and Phentolamine have a 90 day hold time.

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**OBSERVATION 6**

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, there is no written procedure addressing what steps would be taken to decontaminate the area if there is a broken or spilled vial of beta-lactam products.

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 OF THIS PAGE**

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Larry K. Austin, Investigator  
 Marie A. Fadden, Investigator

*Larry K. Austin*  
*Marie A. Fadden*

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