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: www.fda.gov/oc/industry	08/06/2014 - 08/21/2014* FEI NUMBER 3007181436

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles A Lindstrom, RPh., Owner

FIRM NAME	STREET ADDRESS
Nora Apothecary and Alternative Therapies, Inc.	1101 E 86th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46240-3729	Producer of Sterile Drugs

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 I OBSERVED:

OBSERVATION 1

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, the firm has not performed any sterility testing of sterile processed ophthalmic drugs. For example:

Vancomycin 25 mg/mL, Rx 833772, processed on 5/5/2014
Cyclosporin 1% Suspension, Rx 834991 processed on 6/19/2014

OBSERVATION 2

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

Specifically, environmental monitoring of the [redacted] (b) (4) does not occur each time a sterile ophthalmic drug is formulated therein. For example :

Vancomycin 25 mg/mL, Rx 835433 processed on 7/10/2014
EDTA 1%, Rx 834105 processed on 7/18/2014
Amikacin 40, Rx 833412 processed on 5/28/2014

OBSERVATION 3

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

Specifically, the firm fails to assure that each batch of processed sterile ophthalmic drug meets approropriate potency limits prior to distribution. For example

Scopolamine 0.25% O.D., Rx 833107, processed on 7/1/2014
Tobramycin 14mg/mL O.D.,Rx 835876, processed on 7/23/2014
Timolol 0.25 % O.D., Rx 833295, processed on 7/31/2014

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Larry K. Austin, Investigator LKA

DATE ISSUED
08/21/2014

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: www.fda.gov/oc/industry	08/06/2014 - 08/21/2014* FEI NUMBER 3007181436

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles A Lindstrom, RPh., Owner

FIRM NAME	STREET ADDRESS
Nora Apothecary and Alternative Therapies, Inc.	1101 E 86th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46240-3729	Producer of Sterile Drugs

OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, the [redacted] (b) (4) is in an unclassified area.Examples of drugs processed in the [redacted] (b) (4) are:

Tobramycin 14 mg/mL, Rx #835177, produced on 6/26/2014
EDTA 1%, Rx #834105, produced on 7/18/2014
Vancomycin 25 mg/mL, Rx #835872, produced on 7/30/2014

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the [redacted] (b) (4) used for sterilzation of drug products has not been qualified for each drug product as to absorption and adsorption characteristics.

PHMB 0.02% O.D. Rx # 833338, produced on 5/7/2014
EDTA 1. 0 % O.D., Rx # 834105, produced on 5/16/2014
Glutathione 100 mg/mL, Rx #834775, produced on 6/12/2014

OBSERVATION 6

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

Specifically, there is no stability data for any sterile ophthalmic drugs processed by this firm including Amikacin 40 (9 day BUD), Scopolamine 0.25% O.D. (3 day BUD) and Cyclosporin 2% (9 day BUD).

*** DATES OF INSPECTION:**
08/06/2014(Wed), 08/08/2014(Fri), 08/21/2014(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Larry K. Austin, Investigator Larry K Austin	08/21/2014