



**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 23, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *DLG*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Nora Apothecary & Alternative Therapies Recall

SUGGESTED

ACTION: Unclassified Recall; All sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product, and dispensed by the pharmacy on or before Friday, April 19, 2013. The recall is being initiated due to concerns associated with quality control processes that present a lack of sterility assurance and were observed during a recent FDA inspection; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recall includes sterile products that Nora Apothecary & Alternative Therapies supplied to patients and offices of licensed medical professionals. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nora Apothecary & Alternative Therapies Announces a Voluntary Multi-State Recall of All Sterile Compounded Products Due to a Lack of Sterility Assurance

Contact:

Consumer

(317)251-9547

(800)729-0276

FOR IMMEDIATE RELEASE - April 22, 2013 - Indianapolis, Indiana - Nora Apothecary & Alternative Therapies today announced a voluntary multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product. The compounded products that are subject to the recall are those products within their expiration date that were compounded and dispensed by the pharmacy on or before Friday, April 19, 2013. The recall is being initiated due to concerns associated with quality control processes that present a lack of sterility assurance and were observed during a recent FDA inspection.

Patients are at increased risk for serious infections in the event a sterile product is compromised. To date, Nora has received no reports of injury or illness associated with the use of our sterile products. Patient safety is our highest priority and, out of an abundance of caution, we have decided to initiate this voluntary recall to include all sterile products that are within their expiry periods.

The recall includes sterile products that Nora Apothecary & Alternative Therapies supplied to patients and offices of licensed medical professionals. Specifically, the recall includes approximately 95 dosage units of sterile compounded products that the pharmacy supplied to offices of twelve licensed medical professionals located within Indiana. Some patients that received products from those medical professionals may be live in states other than Indiana. The recall also includes approximately 400 prescriptions compounded for patients within Indiana and four other states: four prescriptions for patients in Illinois; and one prescription each for patients in Ohio, Florida and Tennessee. A list of products is attached. Nora Apothecary & Alternative Therapies will be notifying customers by phone, fax, mail, or personal visits to return the products to the pharmacy.

Consumers or health care providers with questions regarding this recall may contact Nora Apothecary & Alternative Therapies by phone at 800-729-0276 or 317-251-9547 from the hours of 9:30AM- 6:00PM Eastern Daylight Time Monday through Friday, or at the following e-mail address: pharmacist@noraapothecary.com. Patients who have received any product furnished by Nora Apothecary & Alternative Therapies and have concerns should contact their healthcare provider.

Adverse reactions or quality problems experienced with the use of any Nora Apothecary & Alternative Therapies' products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Online: www.fda.gov/medwatch/report.htm¹
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm².
Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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[RSS Feed for FDA Recalls Information³ \[what's this?⁴\]](#)

[Nora Apothecary & Alternative Therapies Product List](#)