



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 21, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program
SUBJECT: Unique Pharmaceuticals, Ltd. - RECALL [Drug]

AFFECTED PRODUCT: Sterile Drug Compounded Preparations

SUMMARY: Unclassified Recall; The recall is due to FDA's concerns associated with Unique's compounding facilities and compounding processes that FDA contends present a lack of sterility assurance and were observed during recent FDA inspections.

The recall includes all sterile compounded preparations that Unique has supplied to its customers within expiry. Non-sterile preparations are not affected by this recall. The affected products were distributed in syringes, vials, and bags.

The products were sold nationwide.

SUGGESTED ACTION: For consumer inquiry only. Consumers or health care providers with questions regarding this recall may contact Unique by phone at [888-339-0874] from the hours of 9 a.m to 5 p.m. CST Central Time, Monday through Friday, or at the following e-mail address: recall@upisolutions.com

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.



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To promote and provide
essential public health services.

Unique Pharmaceuticals, Ltd. Announces a Voluntary Nationwide Recall of all Sterile Compounded Preparations Within Their Expiry Period Due to a Lack of Sterility Assurance

Contact:
Consumer:
888-339-0874
recall@upisolutions.com

FOR IMMEDIATE RELEASE - July 19, 2014 - Unique Pharmaceuticals, Ltd., ("Unique" or "the Company") today announced a voluntary nationwide recall of all sterile drug preparations compounded by the outsourcing facility that have not reached the expiration date listed on the products. Unique is initiating the recall due to FDA's concerns associated with Unique's compounding facilities and compounding processes that FDA contends present a lack of sterility assurance and were observed during recent FDA inspections.

In the event a sterile product is compromised, patients are at risk for serious and possible life-threatening infections. To date, Unique has received no reports of injury or illness associated with the use of its sterile preparations. Patient safety is Unique's highest priority, and Unique has proceeded with this voluntary action out of an abundance of caution.

The recall includes all sterile compounded preparations that Unique has supplied to its customers within expiry. Non-sterile preparations are not affected by this recall. The affected products were distributed in syringes, vials, and bags.

The preparations covered by this recall were distributed nationwide. Until further notice, health care providers should stop using all lots of sterile products prepared by Unique that are within their expiry period and return them to the Company.

Unique will be notifying customers by phone, fax, mail, or personal visits to return the products to the Company.

Consumers or health care providers with questions regarding this recall may contact Unique by phone at [888-339-0874] from the hours of 9 a.m to 5 p.m. CST Central Time, Monday through Friday, or at the following e-mail address: recall@upisolutions.com

Adverse reactions or quality problems experienced with the use of any Unique's preparations 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.htm
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. 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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