Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: December 19, 2013

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

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

SUBJECT: Abrams Royal Pharmacy [Drug]

AFFECTED PRODUCT: **All unexpired lots of sterile products. *Sterile products are injectable medications, IVs, eye drops, pellet implants, nasal sprays, inhalation solutions, and eye ointments.***

SUMMARY: **Unclassified Recall; The recall is due to concerns of lack of sterility assurance. All recalled products have a label that includes Abrams Royal Pharmacy's name and phone as well as a lot number. While not every label contains an expiration date, consumers can call the pharmacy with the lot number and find out the expiration date.**

Dispensed nationwide. The recalled products were distributed to health care facilities, physicians, and patients from June 17, 2013, through December 17, 2013.

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Abrams Royal Pharmacy has begun notifying its customers by mail and is arranging for the return of all recalled medication. To return product or request assistance related to this recall, users should contact Abrams Royal at 214-349-8000, Monday through Friday, between 9:00 a.m. and 5:00 p.m. CST. Furthermore, if any recalled products are found, notify this office at 317-233-8475.**

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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.

Abrams Royal Pharmacy Issues Voluntary Nationwide Recall of All Lots of Unexpired Sterile Products Due to Lack of Sterility Assurance

Contact
Consumer:
214-349-8000

Media:
David Ball, david@ballcg.com
Greg Turner, greg@ballcg.com
617-243-9950

FOR IMMEDIATE RELEASE - December 18, 2013 - Abrams Royal Pharmacy is voluntarily recalling all unexpired lots of sterile products dispensed nationwide due to concerns of lack of sterility assurance. All unexpired lots of sterile compounded products are subject to the recall. Sterile products are injectable medications, IVs, eye drops, pellet implants, nasal sprays, inhalation solutions, and eye ointments.

All recalled products have a label that includes Abrams Royal Pharmacy's name and phone as well as a lot number. While not every label contains an expiration date, consumers can call the pharmacy with the lot number and find out the expiration date.

The recall was issued after a single, isolated report of an adverse event involving a patient in California who received a compounded medication from the pharmacy. Out of an abundance of caution, Abrams Royal is voluntarily recalling all sterile products within expiry. If there is microbial contamination in products intended to be sterile, patients are at risk for serious, potentially life-threatening infections.

The recalled products were distributed to health care facilities, physicians, and patients from June 17, 2013, through December 17, 2013.

Abrams Royal Pharmacy has begun notifying its customers by mail and is arranging for the return of all recalled medication. To return product or request assistance related to this recall, users should contact Abrams Royal at 214-349-8000, Monday through Friday, between 9:00 a.m. and 5:00 p.m. CST.

Customers that have product which is being recalled should stop using it and contact the pharmacy to arrange for return of unused product. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using these products. Adverse reactions may be reported to the FDA's MedWatch program via: