Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 12, 2013

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

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

SUBJECT: Leiter's Compounding Pharmacy Recall [Drug]

AFFECTED PRODUCT:
Bevacizumab Lot No. 08052013@1, expiry 11/03/13
Bevacizumab Lot No. 08052013@4, expiry 11/03/13
Lidocaine/phenylephrine Lot No. 07302013@6, expiry 10/28/13

SUMMARY: **Unclassified Recall; Leiter's Compounding Pharmacy is voluntarily recalling 3 lots of its sterile products due to concerns of sterility assurance with Front Range Laboratories, Leiter's Compounding Pharmacy's independent testing laboratory. The FDA investigators observed that methods used by the independent laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. The FDA has concerns that results obtained from the laboratory are not reliable. From the information provided by FDA, these products were dispensed to health care providers between 8/05/13 to 9/02/13 nationwide throughout the United States.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax or e-mail. Additionally, be aware of this recall in case of consumer concern. Direct all consumers to contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product. To return product or request assistance related to this recall, users should contact Leiter's Compounding Pharmacy at 1-800-292-6772, Monday through Friday, between 8:00 a.m. and 5:00 p.m. PST. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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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

Leiter's Compounding Pharmacy Issues Voluntary Nationwide Recall of Three Product Lots Due to Lack of Assurance of Sterility Concerns Related to its Independent Testing Vendor

Contact
Consumer:
Leiter's Compounding Pharmacy
1-800-292-6772

Media:
Greg Turner, Ball Consulting Group, LLC
617-243-9950 / greg@ballcg.com

FOR IMMEDIATE RELEASE –September 10, 2013 – Leiter's Compounding Pharmacy is voluntarily recalling 3 lots of its sterile products due to concerns of sterility assurance with Front Range Laboratories, Leiter's Compounding Pharmacy's independent testing laboratory. The following products and lot numbers are subject to the nationwide recall:

- Bevacizumab Lot No. 08052013@1, expiry 11/03/13
- Bevacizumab Lot No. 08052013@4, expiry 11/03/13
- Lidocaine/phenylephrine Lot No. 07302013@6, expiry 10/28/13

The use of a non-sterile injectable product exposes patients to the risk of contracting serious life-threatening infections. Leiter's Compounding Pharmacy has not received any reports of adverse events or reports of contamination but decided to recall the products following a recent inspection by the FDA of Front Range Laboratories. The FDA investigators observed that methods used by the independent laboratory to assess sterility may have resulted in pharmacies receiving inaccurate laboratory test results. The FDA has concerns that results obtained from the laboratory are not reliable.

These products were dispensed to health care providers between 8/05/13 to 9/02/13 nationwide throughout the United States.

Leiter's Compounding Pharmacy is notifying prescribing Physicians by first class mail, telephone, and/or email and is arranging for return of all recalled products. Facilities that have product which is being recalled should stop using and return to Leiter's Compounding Pharmacy, as indicated by the instructions below.

To return product or request assistance related to this recall, users should contact Leiter's Compounding Pharmacy at 1-800-292-6772, Monday through Friday, between 8:00 a.m. and 5:00 p.m. PST.

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

"After receiving an FDA report of potential testing errors at Front Range, we quickly decided to recall any products associated with the inspection, because we believe it is the most prudent course," said Charles Leiter, Pharm.D, President of Leiter's Compounding Pharmacy. "We are

working hard to minimize any impact on our valued customers as we continue to provide high-quality compounded medications to patients."

Adverse reactions or quality problems experienced with the use of this product 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[1]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. 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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