Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 10, 2013

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

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

SUBJECT: Avella Specialty Pharmacy Recall [Drug]

AFFECTED PRODUCTS: **Bevacizumab 1.25 mg/0.05 mL PF Lot #12-20130508@179 Expiry 11/3/2013**
Vancomycin PF (BSS) 1% Lot #12-20130508@181 Expiry 10/4/2013
Due to Concerns of the Sterility of the Products

SUGGESTED ACTION: **Unclassified Recall; Avella Specialty Pharmacy is voluntarily recalling two compounded sterile medications. Avella was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used to assess sterility and other qualities (e.g. strength and stability) which may have resulted in Avella receiving inaccurate laboratory test results on the specified lots. FDA has raised concerns that test results obtained from Front Range Labs may not be reliable. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were dispensed directly to healthcare providers nationwide. The medications can be identified based on product label and corresponding medication name and lot number. Detail store information is not available at this time. In addition, 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.

Avella Specialty Pharmacy Issues Voluntary Nationwide Recall of Two Medications
Due to Concerns of Sterility Assurance at Testing Vendor

Contact

Patients and Providers:
Avella Specialty Pharmacy
QA@avella.com
877-738-0797

Media:
Amy Hansen
amy@seroka.com
262-523-3740

FOR IMMEDIATE RELEASE – September 9, 2013 – Avella Specialty Pharmacy is voluntarily recalling two compounded sterile medications. The recall is a result of concerns of sterility assurance with the specialty pharmacy's independent testing laboratory, Front Range Laboratories. Avella is recalling the following medications:

Product	Lot Number	Expiry
Bevacizumab 1.25 mg/0.05 mL PF	12-20130508@179	11/3/2013
Vancomycin PF (BSS) 1%	12-20130508@181	10/4/2013

Avella was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used to assess sterility and other qualities (e.g. strength and stability) which may have resulted in Avella receiving inaccurate laboratory test results on the specified lots. FDA has raised concerns that test results obtained from Front Range Labs may not be reliable. Therefore, Avella decided to conduct this voluntary recall out of an abundance of caution. Avella has discontinued its relationship with Front Range Labs as a result of this issue.

If microbial contamination occurs in medications intended to be sterile, patients are at risk of serious infections that may be life threatening. To date, Avella has not received **any** reports of adverse events related to the recall. The recalled products were dispensed directly to healthcare providers nationwide. The medications can be identified based on product label and corresponding medication name and lot number.

Avella Specialty Pharmacy is notifying customers of the voluntary recall by phone and mail. Customers that have any of the medications that are being recalled should immediately discontinue use and return the unused portion to Avella.

Patients and healthcare providers with questions regarding this recall can contact Avella at (877) 738-0797 Monday through Friday between 6am and 6pm Pacific Standard Time or via e-mail at

QA@avella.com. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions 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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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[6]

Avella Specialty Pharmacy Issues Voluntary Nationwide Recall of Two Medications
Due to Concerns of Sterility Assurance at Testing Vendor
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