Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 26, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Downing Labs, LLC – RECALL [Drug]

AFFECTED PRODUCT: **Sterile products compounded and packaged by Downing Labs**

SUMMARY: **Unclassified Recall; The recall is due to concerns over sterility assurance.**

All lots of sterile products compounded and packaged by Downing Labs and that remain within expiry. The recall does not pertain to any non-sterile compounded medications prepared by Downing Labs.

The products were distributed nationwide between April 20, 2015 and September 15, 2015.

SUGGESTED ACTION: **For consumer inquiry only. Contact Downing Labs at 800-914-7435 from the hours of 8:30AM-5:00PM central time Monday-Friday, or e-mail at pharmacist@downinglabs.com to discuss the return of any unused sterile compounded products.**

****

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.

Recall: Firm Press Release
Downing Labs, LLC Issues Voluntary Nationwide Recall of All Sterile Compounded Products Due to Lack of Sterility Assurance
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.

For Immediate Release

October 20, 2015

Contact

Consumers

Name
pharmacist@downinglabs.com
800-914-7435

Media

David Ball, Ball Consulting Group, LLC
david@ballcg.com
617-243-9950

Firm Press Release

FOR IMMEDIATE RELEASE – October 20, 2015 – Farmers Branch, TX – Downing Labs, LLC ("Downing Labs") is voluntarily recalling all lots of sterile products compounded and packaged by Downing Labs and that remain within expiry due to concerns over sterility assurance. The products were distributed nationwide and in the UK to patients and providers between April 20, 2015 and September 15, 2015. The recall does not pertain to any non-sterile compounded medications prepared by Downing Labs.

If there is a contamination in products intended to be sterile, patients are at risk of serious infections which may be life threatening. There have been no consumer complaints or reports of any issues with the recalled products to date. Downing Labs takes this measure voluntarily and solely out of an abundance of caution because Downing Labs takes the utmost care to ensure patient safety. Thus, Downing Labs is asking all patients and providers that received sterile compounded products from Downing Labs between April 20, 2015 and September 15, 2015 that remain within expiry to take the following actions:

1. Discontinue use of the products;
2. Set aside any unused product until further instructions are received on how to return the product; and
3. Contact Downing Labs at 800-914-7435 from the hours of 8:30AM-5:00PM central time Monday-Friday, or e-mail at pharmacist@downinglabs.com to discuss the return of any unused sterile compounded products.

Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Providers who have dispensed any sterile product distributed by Downing Labs to a patient(s) for use outside of the provider's office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall.

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

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the FDA.

Again, no consumer complaints have been received. Downing Labs' primary concern is your safety and thus Downing Labs is taking this action out of an abundance of caution. Thank you for your continued support.

###