Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 2, 2013

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

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

SUBJECT: Fresenius Kabi USA Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; Four lots of Benztropine Mesylate Injection, USP, 2 mg/2mL (1mg/mL) in 2 mL single dose vials due to the potential presence of glass particles (glass delamination) in the vials; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. All customers who received the recalled vials are being notified and instructed to return any unused product to Fresenius Kabi USA. Detail store information is not available at this time. In addition, if any recalled products are found, please 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.

Fresenius Kabi USA Issues Voluntary Nationwide Recall of Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), in 2 mL Single Dose Vials

Contact
Consumer:
888-386-1300

Media:
Matt Kuhn
847-220-3033

FOR IMMEDIATE RELEASE - June 30, 2013 - LAKE ZURICH, Ill. - Fresenius Kabi USA is voluntarily recalling four lots of Benztropine Mesylate Injection, USP, 2 mg/2mL (1mg/mL) in 2 mL single dose vials due to the potential presence of glass particles (glass delamination) in the vials. This recall is being conducted to the user level.

The product is manufactured by Allergy Laboratories, Inc. and distributed by Fresenius Kabi USA. The product may appear with "APP" or "Nexus Pharmaceuticals" labels (see table). The recalled lots are:

Product Name/ Strength/Size	NDC Number	Label	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), 2 mL Single Dose Vial	14789-300-02	Nexus		030712	03/2014	05/18/2012	09/24/2012
		Nexus	1478930002	071212	07/2014	09/21/2012	10/15/2012
		Nexus		090512	09/2014	10/10/2012	11/20/2012
	63323-970-02	APP	970102	111412	11/2014	02/06/2013	05/31/2013

No adverse events, patient reactions or customer complaints have been reported to date. The company has discontinued distribution of Benztropine Mesylate while it investigates the cause.

All customers who received the recalled vials are being notified and instructed to return any unused product to Fresenius Kabi USA.

The administration of glass particulate, if present in a parenteral drug, poses a potential safety risk to patients. Case reports suggest that sequelae of thromboembolism, some life-threatening (such as pulmonary emboli), may occur. There have also been reports in the literature of particulate possibly causing phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, subsequent generation of microthrombi, and emboli. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Administration of a glass particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material and are typically non-serious.

The defect discovered in this product was noted as visible particulate. However, the process of glass delamination may result in formation of visible and subvisible particles.

Benztropine Mesylate is used as an adjunct in the therapy of all forms of Parkinsonism. It is useful also in the control of extrapyramidal disorders due to neuroleptic drugs, except tardive dyskinesia.

To report adverse events or quality problems experienced with the use of this product, call Fresenius Kabi USA's Vigilance and Medical Affairs at 1-800-551-7176, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (Central Time), or by e-mail at appmedicalinfo@APPpharma.com.

Any 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.

- **Online**: http://www.fda.gov/MedWatch/report.htm[1]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://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.

Additional Fresenius Kabi contact information

Health care professionals can find additional information about the recall on the company's web site (www.apppharma.com/our-products/product-updates[3]) or by calling Fresenius Kabi USA Quality Assurance at 1-866-716-2459, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (Central Time).

Questions regarding product availability and ordering can be directed to Fresenius Kabi USA Customer Service at 1-888-386-1300, Monday through Friday, between the hours of 7 a.m. and 6 p.m. (Central Time).

Fresenius Kabi USA is the U.S. subsidiary of Fresenius Kabi, a global health care company that focuses on medicines and medical devices used to care for critically and chronically ill patients inside and outside the hospital.

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