Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 5, 2013

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

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

SUBJECT: Nexus Pharmaceuticals Inc. Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; Two lots of Benztropine Mesylate Injection, USP, 2 mg/2mL (1mg/mL) in 2 mL single dose vials due to the potential presence of visible particulate matter in the vials. This recall is being conducted at the user level; 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. Nexus Pharmaceuticals is notifying its distributors and is arranging for return of all recalled products. 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.

Nexus Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), in 2 mL Single Dose Vials

Contact
Consumer:
888-806-4606

Media:
Omair Ahmed
847-996-3790
oahmed@nexuspharma.net

FOR IMMEDIATE RELEASE - August 1st, 2013 - Nexus Pharmaceuticals Inc. is voluntarily recalling two lots of Benztropine Mesylate Injection, USP, 2 mg/2mL (1mg/mL) in 2 mL single dose vials due to the potential presence of visible particulate matter in the vials. This recall is being conducted at the user level.

The product is manufactured by Allergy Laboratories, Inc. and was distributed by Nexus Pharmaceuticals Inc. The recalled lots are:

Product Name/Strength/Size	Benztropine Mesylate Injection, USP 2 mg/2 mL (1 mg/mL), 2 mL Single Dose Vial
NDC Number	14789-300-02
Label	Nexus
Product Code	1478930002
Lot Numbers	030712, 112911
Expiration Dates	03/2014, 11/2013
First Ship Dates	03/26/2012, 12/15/2011
Last Ship Dates	05/17/2012, 3/26/2012

No adverse events, patient reactions or customer complaints have been reported to date. Nexus Pharmaceuticals is notifying its distributors and is arranging for return of all recalled products. Any questions about returning unused products should be directed to the customer call center at 888-806-4606 Monday through Friday, Between the hours of 8 a.m. and 6 p.m. (Central Time).

The administration of 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 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 using higher magnification. 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 Nexus Pharmaceuticals Inc. Medical Affairs at 1-877-913-2720, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (Central Time), or by e-mail at sales@nexuspharma.net.

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.

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

Photo: Product Labels[5]