Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: January 18, 2013

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

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

SUBJECT: Advance Pharmaceutical Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; voluntary nationwide recall of one lot of Ferrous Sulfate Tablets, 325 mg, Lot 12G468 Exp. 07/14, UPC Barcode 0 0536-5890-01 3 because a pharmacist complaint that a bottle of Ferrous Sulfate Tablets, 325 mg 07-2014, contained Meclizine HCl 25 mg tablets, NDC 0536-3990-01; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product was distributed in the State of Indiana. Meclizine toxicity may lead to dose-related serious adverse events, including impaired alterness, drowsiness, confusion, low blood pressure, coma, and respiratory depression. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Advance Pharmaceutical Issues Nationwide Voluntary recall of one Lot (# 12G468) of Ferrous Sulfate Tablets, 325 mg, that may actually contain Meclizine HCl 25 mg tablets

Contact:
Consumer:
Advance Pharmaceutical Inc.
Ph: 631-981-4600, Ext. 300

FOR IMMEDIATE RELEASE - January 17, 2013 - Advance Pharmaceutical Inc. today announced that it is conducting a voluntary nationwide recall of one lot of Ferrous Sulfate Tablets, 325 mg, Lot 12G468 Exp. 07/14, UPC Barcode 0 0536-5890-01 3. The lot was manufactured and packaged in 100 count bottles by Advance Pharmaceutical Inc. under the label of Rugby NATURAL IRON SUPPLEMENT Ferrous Sulfate. Advance Pharmaceutical Inc. initiated the recall on December 28, 2012 because they received a pharmacist complaint that a bottle of Ferrous Sulfate Tablets, 325 mg 07-2014, contained Meclizine HCl 25 mg tablets, NDC 0536-3990-01. Taking Meclizine HCl 25 mg as Ferrous Sulfate 325 mg may cause serious side effects to those who consume alcohol or other sedatives, those with a pre-existing CNS disorder, those with imprinted kidney or liver function, the elderly, nursing infants of lactating mothers who received the drug and newborns of mothers who received the drug immediately before childbirth.

Consumers who take three tablets daily of the defective product for treatment of iron deficiency will would be inadvertently ingesting 75 mg of meclizine HCl daily, which is close to the maximum daily adult dose in prescription meclizine drug products of 100 mg. Consumption of meclizine three times a day instead of once daily as monograph recommended is likely to lead to significant drug accumulation because it is a long-acting drug with effects that may persist up to 24 hours after a single dose. Meclizine toxicity may lead to dose-related serious adverse events, including impaired alterness, drowsiness, confusion, low blood pressure, coma, and respiratory depression. Without supportive treatment meclizine toxicity has the potential to be life-threatening.

Consumers who have the affected lot may contact Advance Pharmaceutical with questions at 631-981-4600, Ext.300 on Monday through Friday between 8:30 am and 4:30 pm ET.

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**: 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]