Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: February 18, 2011

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

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

SUBJECT: Upsher-Smith Laboratories, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Jantoven® Warfarin Sodium, USP, 3mg Tablets, an anticoagulant with an expiration date of September 2012, NDC # 0832-1214-00 after a single bottle labeled as Jantoven® Warfarin Sodium, USP, 3mg Tablets was found to contain tablets at a higher, 10mg strength before it was dispensed ; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The product lot was distributed to wholesalers, retail chains and independent pharmacies throughout the United States. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

Upsher-Smith Laboratories Announces The Voluntary Nationwide Recall Of Jantoven® Warfarin Sodium Tablets, USP, 3mg, Due To Mislabeled Bottles

Contact:
Upsher-Smith Information Line
1-888-650-3789

FOR IMMEDIATE RELEASE - February 16, 2011 - Upsher-Smith Laboratories, Inc., of Maple Grove, Minnesota is voluntarily recalling one lot (lot #284081) of Jantoven® Warfarin Sodium, USP, 3mg Tablets, an anticoagulant with an expiration date of September 2012, NDC # 0832-

1214-00. The company is initiating the recall as a precautionary measure after a single bottle labeled as Jantoven® Warfarin Sodium, USP, 3mg Tablets was found to contain tablets at a higher, 10mg strength before it was dispensed. To date, the company has identified no additional mislabeled bottles.

At Upsher-Smith, patient safety is of foremost concern. The primary risk of substituting 10mg warfarin for 3mg warfarin is overdosing more than 3 times the labeled amount which leads to excessive anticoagulation that could be expected to result in life-threatening hemorrhage in patients.

Consistent, continuous dosing of warfarin is necessary for optimal care for many ill patients. For this reason, patients' doses must be adjusted by regular measurements of the degree of anticoagulation to assure warfarin use is safe and effective. Either abrupt interruption of this medication, or administration of an inappropriately high dose, could present a serious health risk. Patients should check with their health care provider regarding the appropriateness of their current therapy prior to making any change.

The two Jantoven tablets can be readily identified by color: the 3mg tablet is tan and the 10mg tablet is white. In addition, the 3mg tablet is imprinted with the letters WRF, a line, and the number 3 below the line. The reverse side of the 3mg tablet carries the number 832. The 10mg tablet is imprinted with the letters WRF, a line, and the number 10 below the line. The reverse side of the 10mg tablet carries the number 832.

Upsher-Smith Laboratories is working cooperatively with the U.S. Food and Drug Administration to implement a nationwide recall as quickly and efficiently as possible.

The product lot was distributed to wholesalers, retail chains and independent pharmacies throughout the United States. The company is notifying its pharmacy customers and wholesalers, and arranging for the return of all recalled product. The product was packaged at the Upsher-Smith plant in Plymouth, Minnesota.

Consumers and pharmacists can call the Upsher-Smith medical information line at 1-888-650-3789 for more information and to access product details, Monday-Friday between 8:00 a.m. and 5:00 p.m. (CST).

Any adverse reactions 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[9]
- Regular: Use postage-paid, pre addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[10]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

About Upsher-Smith
Upsher-Smith Laboratories, Inc., founded in 1919, is a privately held pharmaceutical company that develops, manufactures and markets prescription and over-the-counter products. Upsher-Smith's product portfolio focuses in the areas of women's health, dermatology, cardiology, and CNS diseases. Upsher-Smith is headquartered in Maple Grove, Minn.

Photo: Product Labels[14]