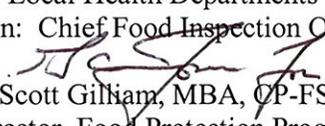




Mitchell E. Daniels, Jr.
Governor

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

DATE: February 21, 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. Expanded Recall

SUGGESTED

ACTION: Unclassified Recall; Jantoven® Warfarin Sodium, USP, 3 mg Tablets; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The products affected were 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.

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 Expansion of Voluntary Nationwide Recall. Affected Products Include Amantadine, Amlodipine, Androxy, Baclofen, Bethanechol, Jantoven® and Oxybutynin

Contact:
Elizabeth Likly
Kovak-Likly Communications
203-762-8833
elikly@klcpr.com

FOR IMMEDIATE RELEASE - February 18, 2011 - Upsher-Smith Laboratories, Inc., of Maple Grove, Minnesota is voluntarily expanding its previously announced recall of Jantoven® Warfarin

Sodium, USP, 3 mg Tablets to include additional products that were packaged on the same packaging line between May 17, 2010 and November 17, 2010. The company is initiating the recall as a precautionary measure after a bottle labeled as Jantoven® Warfarin Sodium, USP, 3 mg Tablets was found by a retail pharmacy to contain tablets at a higher, 10 mg strength.

At Upsher-Smith, patient safety is of foremost concern. The substitution of warfarin, or any other product, may lead to a change in the therapeutic effect of the intended drug.

Consistent, continuous dosing of any product is necessary for optimal care for many ill patients. Patients should check with their health care provider regarding the appropriateness of their current therapy prior to making any change.

The expanded recall includes the following products:

Product	Batch Number	Expiration Date	Product Identification
Amantadine 100 mg (100-ct bottles)	284166	Aug-12	Peach; imprinted AMT, 832
Amantadine 100 mg (100-ct bottles)	280603	Jul-12	Peach; imprinted AMT, 832
Amantadine 100 mg (100-ct bottles)	283797	Jul-12	Peach; imprinted AMT, 832
Amlodipine 5 mg (90-ct bottles)	280564	May-12	White; scored; imprinted ALP, 5, 832
Amlodipine 5 mg (90-ct bottles)	282661	Aug-12	White; scored; imprinted ALP, 5, 832
Androxy 10 mg (100-ct bottles)	283336	Sep-12	Green; scored; imprinted 86, 832
Baclofen 10 mg (90-ct bottles)	284651	Sep-12	White; scored; imprinted BAC, 10, 832
Baclofen 10 mg (90-ct bottles)	282346	Aug-12	White; scored; imprinted BAC, 10, 832
Baclofen 10 mg (90-ct bottles)	281664	Aug-12	White; scored; imprinted BAC, 10, 832
Bethanechol 5 mg (100-ct bottles)	282255	Aug-12	White; scored; imprinted BCL, 5, 832
Bethanechol 10 mg (100-	280569	Jun-12	White; scored; imprinted

ct bottles)			BCL, 10, 832
Bethanechol 25 mg (100-ct bottles)	280567	Jun-12	Yellow; scored; imprinted BCL, 25, 832
Jantoven 1 mg (100-ct bottles)	280617	Mar-12	Pink; scored; imprinted WRF, 1, 832
Jantoven 1 mg (100-ct bottles)	282872	Jul-12	Pink; scored; imprinted WRF, 1, 832
Jantoven 2 mg (100-ct bottles)	280598	Jun-12	Lavender; scored; imprinted WRF, 2, 832
Jantoven 2.5 mg (100-ct bottles)	281667	Jul-12	Green; scored; imprinted WRF, 2 ½, 832
Jantoven 3 mg (100-ct bottles)	280612	Jun-12	Tan; scored; imprinted WRF, 3, 832
Jantoven 3 mg (100-ct bottles)	284081	Sep-12	Tan; scored; imprinted WRF, 3, 832
Jantoven 4 mg (100-ct bottles)	283334	Jul-12	Blue; scored; imprinted WRF, 4, 832
Jantoven 5 mg (100-ct bottles)	280581	Jun-12	Peach; scored; imprinted WRF, 5, 832
Jantoven 5 mg (100-ct bottles)	283340	Jul-12	Peach; scored; imprinted WRF, 5, 832
Jantoven 5 mg (100-ct bottles)	283459	Sep-12	Peach; scored; imprinted WRF, 5, 832
Jantoven 5 mg (100-ct bottles)	283455	Jun-12	Peach; scored; imprinted WRF, 5, 832
Jantoven 6 mg (100-ct bottles)	282277	Jun-12	Teal; scored; imprinted WRF, 6, 832
Jantoven 6 mg (100-ct bottles)	284079	Sep-12	Teal; scored; imprinted WRF, 6, 832
Jantoven 7.5 mg (100-ct bottles)	280614	Aug-12	Yellow; scored; imprinted WRF, 7 ½, 832
Jantoven 10 mg (100-ct bottles)	283342	Aug-12	White; scored; imprinted WRF, 10, 832
Jantoven 10 mg (100-ct bottles)	282917	Feb-12	White; scored; imprinted WRF, 10, 832
Oxybutynin 5 mg (100-ct bottles)	283368	Jul-13	White; scored; imprinted 38, 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 products affected were 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 products. These products were packaged at the Upsher-Smith plant in Plymouth, Minnesota.

Consumers and pharmacists can call 1-877-492-4791 for more information and to access product details, Monday-Friday between 8:00 a.m. and 5:00 p.m. (EST).

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 Mail:** 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. For more information, visit www.upsher-smith.com¹¹.