Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 13, 2013

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

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

SUBJECT: Zydus Pharmaceuticals USA Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; One lot of Warfarin 2 mg Tablets, Lot #MM5767, expiration date June 2014 to the retail level. Four tablets of Warfarin 2 mg Tablets, Lot MM5767, have been found to be oversized in one product complaint; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The product was distributed nationwide in the United States to wholesalers/distributors, retailers and mail order providers, from November 2012 to December 2012. 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.

****

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.

Zydus Pharmaceuticals USA Inc. Issues Voluntary Nationwide Recall of Warfarin 2 mg Tablets, Lot MM5767, Expiration Date June 2014, Due to Oversized Tablets

Contact:
Consumer:
Zydus Pharmaceuticals USA Inc.
1-877-993-8779, Option #2

FOR IMMEDIATE RELEASE - June 10, 2013 - Zydus Pharmaceuticals USA Inc. is voluntarily recalling one lot of Warfarin 2 mg Tablets, Lot #MM5767, expiration date June 2014 to the retail

level. Four tablets of Warfarin 2 mg Tablets, Lot MM5767, have been found to be oversized in one product complaint.

Ingestion of a greater than intended dose of Warfarin, could lead to an increased pharmacological effect of warfarin. As a result, patients would be more likely to develop bleeding as an adverse reaction and in some patients that bleeding into a critical organ (mostly the central nervous system) could be fatal. The risk of bleeding is increased if overdosing is repeated continuously on a daily basis.

Zydus has not received any reports of adverse events or any additional product complaint related to this lot to date, but as a precautionary measure, Zydus is recalling lot MM5767 from the distribution.

The product is used as prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE), prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement and reduction in the risk of death, recurrent myocardial infarction (MI), and thromboembolic events such as stroke or systemic embolization after myocardial infarction. Product is packaged in HDPE Bottle of 1000's count, which may have been dispensed to patients in smaller bottles. The only lot affected of Warfarin 2 mg Tablets being recalled is Lot MM5767.

The product can be identified by its NDC #6838205310. The product was distributed nationwide in the United States to wholesalers/distributors, retailers and mail order providers, from November 2012 to December 2012.

Zydus has notified its direct account customers by sending the recall notification letter by FedEx next day air service and is working with customers to arrange for product return.

Anyone with an existing inventory of this particular Lot MM5767 of Warfarin 2 mg Tablets should stop use and distribution, quarantine the recalled lots immediately and call INMAR at 1-800-967-5952 between the hours of 7 a.m. to 4 p.m. CST, Monday through Friday, to arrange for their return. In case patients have tablets of this lot of product, make sure all the tablets are of same size and if unsure, patients should consult their dispensing pharmacy.

If you have any question about product safety issue, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779, Option# 2. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this particular lot of Warfarin 2 mg Tablets.

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: www.fda.gov/medwatch/report.htm [1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Photo: Product Labels[5]