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: July 14, 2010

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

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

SUBJECT: Bristol-Myers Squibb Recall

SUGGESTED ACTION: **Unclassified Recall; 3 lots of physician sample blister packs of Coumadin® 1 mg tablets and 5 lots, of Coumadin 1 mg tablet hospital unit dose (HUD) blister packs; Information provided in case of consumer inquiry**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. The recall only involves Coumadin 1 mg tablet blister-packs distributed in the U.S.

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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.

Bristol-Myers Squibb Initiates a Nationwide Voluntary Recall of Coumadin® 1 mg Tablet Blister Packs

-Recall Involves 1 mg Physician Sample Blister Packs and 1 mg Hospital Blister Packs Only-

FOR IMMEDIATE RELEASE -- July 12, 2010 - Bristol-Myers Squibb initiates a voluntary recall of 3 lots of physician sample blister packs of Coumadin® 1 mg tablets and 5 lots, of Coumadin 1 mg tablet hospital unit dose (HUD) blister packs. The following lot numbers are included in this recall: Physician Sample Blister Packs: Lot# 9A48931A, 9A48931B, 9A48931C,

expiration January 2012; HUD Blister Pack: Lot# 8F34006B, 8K44272A, 8K46168A, 9F44437A

and 9K58012B with expiry dates between June 2011 and November 2012. The recall is a precautionary measure based upon the company's determination that some of the tablets, over time, may not meet specification for isopropanol. Isopropanol is used to maintain the active ingredient, Coumadin, in the crystalline state, and could affect the therapeutic levels of the active ingredient.

Coumadin is prescribed to treat or prevent blood clots. A decrease of active ingredient may increase the risk of clots which could lead to heart attack or stroke and if there is too much active ingredient, there is an increased risk of bleeding.

The recall only involves Coumadin 1 mg tablet blister-packs distributed in the U.S. This recall does not involve Coumadin 1 mg supplied in bottles or any other strengths and dosage forms of the product. Patients who may have product from the subject lots should contact their physicians to ensure that their anticoagulation therapy is not interrupted.

To date, the company has not received any reports of adverse events related to this issue. Bristol-Myers Squibb is committed to ensuring patient safety and is working to resolve this issue quickly and appropriately. The company has notified the U.S. Food and Drug Administration (FDA), and has issued recall communications to all physicians[9] and other customers[10] involved.

Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov[11].

Healthcare professionals and customers may call the following for assistance if they have further questions about the recall:

Recall Logistics	Stericycle 1-877-546-0128
General Inquiries	Bristol-Myers Squibb Customer Relations 1-800-332-2056 (option 1, then option 4)
Medical Inquiries	Bristol-Myers Squibb Medical Information 1-800-321-1335 (option 5)
Recall Reimbursement Process	Bristol-Myers Squibb Customer Service Operations 1-800-631-5244 (option 1, then option 5)