Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 2, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Bristol-Myers Squibb – RECALL [Drug]

AFFECTED PRODUCT: **COUMADIN® FOR INJECTION, 5 mg single-use vials**

SUMMARY: **Unclassified Recall; The recall is due to visible particulate matter found in a small number of Coumadin For Injection unreleased samples.**

COUMADIN FOR INJECTION 5 mg single-use vials is packaged in cartons of six vials. The affected COUMADIN FOR INJECTION includes the following six lots distributed to hospitals and pharmacies from November 2011 through January 2014:

Lot Number	Description	NDC	Expiration
201125	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Sep-2014
201126	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Nov-2014
201127	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Dec-2014
201228	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Jun-2015
201229	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Jul-2015
201230	COUMADIN LINJ 5MG (6VL) US	0590-0324-35	Sep-2015

The recalled product was distributed to hospitals and pharmacies nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Health care professionals and patients may call the following number for assistance if they have further questions about the recall:General and Medical Inquiries:**
Bristol-Myers Squibb Customer Information Center 1-800-332-2056.

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Recall -- Firm Press Release

Bristol-Myers Squibb Issues Voluntary Nationwide Recall of COUMADIN® (Warfarin Sodium) for Injection Due to Presence of Particulate Matter

Contact:
Consumer:
1-800-332-2056

Media:
Laura Hortas
609-252-4587
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FOR IMMEDIATE RELEASE - June 30, 2014 – NEW YORK – Bristol-Myers Squibb Company (NYSE:BMY) is voluntarily recalling six lots of COUMADIN® FOR INJECTION, 5 mg single-use vials in the U.S. This recall is a precautionary measure based on the company's investigation of visible particulate matter found in a small number of COUMADIN FOR INJECTION unreleased samples. Bristol-Myers Squibb believes the safety risk to patients is low, and is further mitigated by the product's prescribing information advising that intravenous drug products be inspected visually prior to administration.

Injected particulate metallic and non-metallic cellulose material can cause serious and potentially fatal adverse reactions such as embolization. Allergic reactions to the foreign material could also occur. To date, there have been no product complaints or adverse events reported to Bristol-Myers Squibb related to this issue.

COUMADIN FOR INJECTION was discontinued in early April 2014. The oral formulation, Coumadin tablets, is not impacted by this recall.

COUMADIN FOR INJECTION is a prescription medicine used to treat blood clots and to lower the chance of blood clots forming in the body. COUMADIN FOR INJECTION is typically administered in a hospital setting by health care professionals to patients not able to receive the oral formulation.

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Bristol-Myers Squibb has issued recall communications to health care professionals and other customers involved and is arranging for return of all recalled products. Anyone that has COUMADIN FOR INJECTION which is being recalled should stop use and distribution and contact Bristol-Myers Squibb's recall vendor, GENCO, at 1-855-838-5784 to arrange for return of remaining stock.

Health care professionals and patients may call the following number for assistance if they have further questions about the recall:

General and Medical Inquiries:
Bristol-Myers Squibb Customer Information Center 1-800-332-2056

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.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail** or **Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

COUMADIN® (warfarin sodium) Prescribing Information (PDF: 172 KB)

About Bristol-Myers Squibb
Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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