Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 30, 2013

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

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

SUBJECT: Cubist Pharmaceuticals, Inc. [Drug]

AFFECTED PRODUCT(S) **CUBICIN® (daptomycin for injection) 500 mg, NDC 67919-011-01, Lot #'s 950453F, 090203F, 201703F, and 201653F.**

SUGGESTED ACTION: **Unclassified Recall; Cubist Pharmaceuticals, Inc. (NASDAQ: CBST) today announced it is voluntarily recalling four lots of CUBICIN® (daptomycin for injection) to the user level due to the presence of particulate matter found in a number of vials from these lots.**

Anyone with an existing inventory of the product lots listed should determine whether they have product from the recalled lots, quarantine and discontinue distribution of all recalled lots of the product and call Cubist at (855) 534-8309 between the hours of 9 a.m. to 7 p.m. EST, Monday through Friday, to arrange for return and replacement of affected lots. In addition, if any recalled products are found, please notify this office at 317-233-3213.

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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.

Cubist Pharmaceuticals Issues Voluntary Nationwide Recall of Four Lots of Cubicin (Daptomycin for Injection) 500mg in 10ml Single Use Vials Due to Presence of Particulate Matter

Contact
Consumer:
(877) 282-4786

Media:
Julie DiCarlo
(781) 860-8063
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FOR IMMEDIATE RELEASE - August 29, 2013 - Lexington, Mass. – Cubist Pharmaceuticals, Inc. (NASDAQ: CBST) today announced it is voluntarily recalling four lots of CUBICIN® (daptomycin for injection) to the user level due to the presence of particulate matter found in a number of vials from these lots.

Product Description	Lot #	Expiration Date	First Ship Date	Last Ship Date
CUBICIN® (daptomycin for injection) 500 mg NDC 67919-011-01	950453F	12/06/2013	05/31/2011	06/27/2011
	090203F	09/07/2014	01/12/2012	01/23/2012
	201703F	08/31/2015	03/4/2013	03/7/2013
	201653F	09/01/2015	03/12/2013	03/18/2013

No adverse events have been reported to date in association with a product complaint of vials containing glass particulates.

Cubist is notifying customers by letter and phone. Anyone with an existing inventory of the product lots listed should determine whether they have product from the recalled lots, quarantine and discontinue distribution of all recalled lots of the product and call Cubist at (855) 534-8309 between the hours of 9 a.m. to 7 p.m. EST, Monday through Friday, to arrange for return and replacement of affected lots.

The administration of glass particulate, if present in an intravenous drug, poses a potential safety risk to patients. Case reports suggest that sequelae of thromboembolism, some life-threatening (such as pulmonary emboli), may occur. There have also been reports in the literature of particulate possibly causing phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, subsequent generation of microthrombi, and emboli. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Administration of a glass particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material and are typically non-serious.

As noted in the package insert for CUBICIN, parenteral drug products should be carefully inspected visually for particulate matter prior to administration. Healthcare providers should not use any CUBICIN vials containing particulate matter.

Patient safety is Cubist's top priority and the Company wants to ensure that patients and the healthcare professionals using CUBICIN are aware of this recall and of what actions, if any, they should take. Cubist is arranging for return of recalled product. An internal investigation has preliminarily identified the root cause as a manufacturing issue with one of our suppliers. Cubist has suspended all manufacturing with the supplier until corrective and preventative measures have been taken.

For healthcare professionals and pharmacists with questions regarding this recall may contact Cubist Medical Information at (877) 282-4786 between the hours of 8 a.m. to 5:30 p.m. EST, Monday through Friday.

Adverse events or quality problems experienced with the use of this product may also be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Online**: http://www.fda.gov/MedWatch/report.htm[1]
- **Regular mail**: use postage-paid, pre-addressed Form FDA3500 available at http://www.fda.gov/MedWatch/getforms.htm[2]
- **Fax**: 1-800-FDA-0178

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

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