Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 21, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Cubist Pharmaceuticals, Inc. - RECALL [Drug]

AFFECTED PRODUCT: **CUBICIN® (daptomycin for injection)**

SUMMARY: **Unclassified Recall; The recall is due** to the presence of particulate matter, identified as glass particles.

Product Description	Lot #	Expiration Date	Ship Dates (MM/DD/YYYY)
CUBICIN® (daptomycin for injection) 500 mg NDC 67919-011-01; UPC 3 67919-011-01 6	280453F	APR 2016	3/17/2014 through 3/25/2014

Cubicin was distributed Nationwide to multiple consignees.

SUGGESTED ACTION: **For consumer inquiry only. Call Cubist at (855) 534-8309 between the hours of 9 a.m. to 7 p.m. EDT, Monday through Friday, to arrange for return and replacement of the affected lot.**

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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 One Lot of CUBICIN (daptomycin for injection) 500 mg in 10 mL single use vials Due to Presence of Particulate Matter

Contact:
Consumer:
Cubist Medical Information
(877) 282-4786

MEDIA:
Julie DiCarlo, (781) 860-8063
Senior Director, Corporate Communications
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FOR IMMEDIATE RELEASE - April 18, 2014 - Cubist Pharmaceuticals, Inc. (NASDAQ: CBST) today announced it is voluntarily recalling one lot of CUBICIN® (daptomycin for injection) to the user level due to the presence of particulate matter, reported via customer complaint and identified as glass particles, found in a single vial from this lot, produced by a contract manufacturer.

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.

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

Cubicin is an intravenously administered prescription product indicated for the treatment of skin infections and certain blood stream infections. Cubicin is supplied in a single-use vial packaged in a carton (refer to www.cubicin.com). The affected Cubicin lot information is contained in the table below. Cubicin was distributed Nationwide to multiple consignees.

Product Description	Lot #	Expiration Date	Ship Dates (MM/DD/YYYY)
CUBICIN® (daptomycin for injection) 500 mg NDC 67919-011-01; UPC 3 67919-011-01 6	280453F	APR 2016	3/17/2014 through 3/25/2014

Cubist is notifying customers by letter and phone. Anyone with an existing inventory of the product lot listed should determine whether they have product from the recalled lot, quarantine

and discontinue distribution of this recalled lot of the product and call Cubist at (855) 534-8309 between the hours of 9 a.m. to 7 p.m. EDT, Monday through Friday, to arrange for return and replacement of the affected lot.

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 identified the root cause as a manufacturing issue with a single manufacturing line of one of our suppliers, and Cubist has suspended all manufacturing on this line.

For healthcare professionals and pharmacists with medical 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. EDT, Monday through Friday.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Complete and submit the report Online:** http://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.

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