



NDA 021572

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Merck Sharpe & Dohme Corp.
Agent for: Cubist Pharmaceuticals, LLC
Attention: Sandra Lynn Wood, Director Global Regulatory Affairs
351 North Sumneytown Pike
PO Box 1000, Mailstop UG2CD48
North Wales, PA 19454

Dear Ms. Wood:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Cubicin (daptomycin for injection) 500 mg/vial, which was approved on September 12, 2003.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 2864-1, which was deferred until August 31, 2015.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a “**DEFERRAL EXTENSION REQUESTED**” in your response. We note that you requested a deferral extension on October 7, 2015; however, we have determined that your request does not qualify for an extension.

In accordance with FDASIA, FDA will post this letter and your response on the website located at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a “**RESPONSE TO PREA NON-COMPLIANCE LETTER.**” To facilitate our review, submit this information to your NDA with a cross-reference letter to the IND to which your protocol has been submitted. In addition, send a copy of the cover letter to CDER’s Division of Pediatric and Maternal Health.

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Joseph G. Toerner, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOSEPH G TOERNER
03/03/2016