DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572/S-009

Cubist Pharmaceuticals, Inc.
Attention: David S. Mantus, PhD
65 Hayden Avenue
Lexington, MA 02421

Dear Dr. Mantus:

Please refer to your supplemental new drug application dated April 27, 2006, received April 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CUBICIN® (daptomycin for injection).

We also acknowledge receipt of your submissions dated July 17, 2006, and October 16, 2006.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for revisions to the "PRECAUTONS, Drug Laboratory Test Interactions" section of the labeling text.

We completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and with the following editorial revisions to the "PRECAUTIONS, Drug-Laboratory Test Interactions" listed below:

Drug-Laboratory Test Interactions

Clinically relevant plasma levels of daptomycin have been observed to cause a significant concentration-dependant false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay. The possibility of an erroneously elevated PT/INR result due to interaction with a recombinant thromboplastin reagent may be minimized by drawing specimens for PT or INR testing near the time of trough plasma concentrations of daptomycin. However, sufficient daptomycin levels may be present at trough to cause interaction.

If confronted with an abnormally high PT/INR result in a patient being treated with Cubicin, it is recommended that clinicians:

1. Repeat the assessment of PT/INR, requesting that the specimen be drawn just prior to the next Cubicin dose (i.e., at trough concentration). If the PT/INR value drawn at trough remains substantially elevated over what would otherwise be expected, consider evaluating PT/INR utilizing an alternative method.

2. Evaluate for other causes of abnormally elevated PT/INR results.

The final printed labeling (FPL) must be identical, and include the editorial revisions indicated, to the enclosed labeling. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD, Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Approved labeling dated May 2006

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

/s/

Janice Soreth

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