DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572/S-011

Cubist Pharmaceuticals, Inc.
Attention: Mary Beth Clark
Director, Regulatory Affairs
65 Hayden Avenue
Lexington, MA 02421

Dear Ms. Clark:

Please refer to your supplemental new drug application dated August 11, 2006, received August 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CUBICIN® (daptomycin for injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the "Post Marketing Experience" section of the labeling text, and in particular the addition of the adverse reaction "pulmonary eosinophilia" under *"Immune System Disorders"*.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling submitted on August 11, 2006. 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, MS, 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: Labeling submitted on August 11, 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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