DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572/S-007

Cubist Pharmaceuticals, Inc.
Attention: Karen L. Drake, Esq.
Director, Regulatory Affairs
65 Hayden Avenue
Lexington, MA 02421

Dear Ms. Drake:

Please refer to your supplemental new drug applications dated September 7, 2005, received September 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cubicin® (daptomycin for injection) intravenous infusion, 500 mg/vial.

We also acknowledge receipt of your submission dated February 9, 2006, received February 10, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following revisions:

1. Removal of disk diffusion information from the label based on the results of Center for Disease Control (CDC) and Clinical Microbiology Institute of Oregon studies which have demonstrated a lack of correlation between daptomycin minimum inhibitory concentration (MIC) by broth microdilution and the zone diameter by disk diffusion for isolates with MIC values $\geq 2\mu g/mL$.

2. Revised structure of daptomycin in the label to reflect the absolute configuration of the asparagine moiety in the side chain as dextrarotatory (D) instead of levarotatory (L).

3. Removal of Cubicin® (daptomycin for injection) 250 mg/vial NDC 67919-010-01 from the labeling text, as the 250 mg vial is no longer distributed.

4. Update of distributor location information in the label.

5. Addition of a US patent number to the label.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the editorial revisions listed in the appended Microbiology portion of the package insert. The final printed labeling (FPL) must include the editorial revisions indicated. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission. "**FPL for approved supplement NDA 21-572/S-007**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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}

James D. Vidra, PhD
Chemistry Team Leader
Division of Anti-Infective and Ophthalmology Products
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure: FDA revisions to the Microbiology portion of package insert
submitted February 15, 2006

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

/s/

Jim Vidra

3/8/2006 10:02:43 AM