DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572/S-010

Cubist Pharmaceuticals, Inc.
Attention: Prabu Nambiar, PhD, MBA, RAC
Senior Director, CMC Regulatory Affairs
65 Hayden Avenue
Lexington, MA 02421

Dear Dr. Nambiar,

Please refer to your supplemental new drug application dated August 2, 2006, received August 3, 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 draft labeling submission dated February 5, 2007, which constitutes a complete response to our approval letter dated October 24, 2006 (S-009), and incorporates proposed revisions to the **"Preparation of CUBICIN for Administration"** section of the package insert, which have been submitted for approval as a provision of this supplement (S-010).

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 draft labeling submitted on February 5, 2007.

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: Draft labeling submitted on February 5, 2007

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
2/12/2007 08:09:19 AM