



NDA 21-572/S-006

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

Dear Dr. Mantus:

Please refer to your supplemental new drug application dated April 13, 2005, received April 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CUBICIN[®] (daptomycin for injection) 250 mg/vial and 500 mg/vial.

This supplemental new drug application provides for the addition of a Post-Marketing Experience subsection to the **ADVERSE REACTIONS** section of the labeling.

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 minor editorial revisions to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections, listed below:

In the subsection entitled "Drug Interactions," under **PRECAUTIONS**, the following phrase should be added to the end of the paragraph under the heading, HMG CoA Reductase Inhibitors: "(see **ADVERSE REACTIONS, Post-Marketing Experience**)."

The following statements should be added to the Post-Marketing Experience subsection under the **ADVERSE REACTIONS** section:

"Post-Marketing Experience"

"The following adverse reactions have been reported with CUBICIN in worldwide post-marketing experience. Because these events are reported voluntarily from a population of unknown size, estimates of frequency cannot be made and causal relationship cannot be precisely established.

"Immune System Disorders: Anaphylaxis; hypersensitivity reactions, including pruritus, hives, shortness of breath, difficulty swallowing, and truncal erythema.

"Musculoskeletal System: Rhabdomyolysis; some reports involved patients treated concurrently with CUBICIN and HMG CoA reductase inhibitors."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling submitted April 13, 2005 and dated August 2004. 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-006.**" 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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: Labeling Submitted on April 13, 2005

**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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