



NDA 21-572/S-022  
NDA 21-572/S-023  
NDA 21-572/S-024  
NDA 21-572/S-027  
NDA 21-572/S-030  
NDA 21-572/S-032

## SUPPLEMENT APPROVALS

Cubist Pharmaceuticals, Inc.  
Attention: David S. Mantus, Ph.D.  
Vice President, Regulatory Affairs  
65 Hayden Avenue  
Lexington, MA 02421

Dear Dr. Mantus:

Please refer to your Supplemental New Drug Applications (sNDA) dated July 29, 2008 (S-022), August 1, 2008 (S-023), September 19, 2008 (S-024), June 30, 2009 (S-027), December 22, 2009 (S-030), and February 17, 2010 (S-032), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cubicin (daptomycin for injection), 500 mg/vial.

We also acknowledged receipt of your amendments dated October 1 and 20, 2010 (S-023) and your labeling amendment dated November 30, 2010. The October 1, 2010, amendment constituted a complete response to our action letter dated March 18, 2010.

These supplemental new drug applications provide for the following:

- **NDA 21-572/S-022:** Revisions to the “**Post-Marketing Experience**” section of the labeling text.
- **NDA 21-572/S-023:** An alternative method of administration of reconstituted CUBICIN at a concentration of 50 mg/mL as an IV bolus injection over approximately 2 minutes.
- **NDA 21-572/S-024:** Revisions to the “**CLINICAL PHARMACOLOGY, Drug-Drug Interactions, Aztreonam**” section of the labeling text.
- **NDA 21-572/S-027:** Proposed content of the label in Physician’s Labeling Rule (PLR) format.
- **NDA 21-572/S-030:** Revisions to the proposed PLR format (S-027) of the label to provide additional information on patients with moderate to severe renal impairment.

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- **NDA 21-572/S-032:** Revisions to Section 6.2 (Post-Marketing Experience) of the proposed PLR-format label to add the adverse reaction “*Clostridium difficile*–associated diarrhea” under “***Infections and Infestations.***”

We have completed our review of these supplemental applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at: <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

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## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

## **REPORTING REQUIREMENTS**

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, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

Katherine A. Laessig, MD  
Deputy Director  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE: Content of labeling dated November 30, 2010

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KATHERINE A LAESSIG  
11/30/2010