



NDA 21-572/S-021

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

Dear Ms. Drake:

Please refer to your supplemental new drug application dated June 27, 2008 received June 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CUBICIN<sup>®</sup> (daptomycin for injection).

We acknowledge receipt of your submission dated September 17, 2008, and your electronic mail correspondence dated February 6, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the "Preparation of CUBICIN<sup>®</sup> for Administration" section of the package insert. Specifically, a new paragraph has been added advising that CUBICIN<sup>®</sup> should not be used in conjunction with ReadyMED<sup>®</sup> elastomeric infusion pumps.

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 listed below:

- Your originally proposed language to be added to the "Preparation of CUBICIN<sup>®</sup> for Administration" section:

[Redacted text] (b)(4)

- Is to be replaced with the following language:

"CUBICIN should not be used in conjunction with ReadyMED<sup>®</sup> elastomeric infusion pumps (Cardinal Health, Inc.). Stability studies of CUBICIN solutions stored in ReadyMED<sup>®</sup> elastomeric infusion pumps identified an impurity (2-mercaptobenzothiazole) leaching from this pump system into the CUBICIN solution."

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the label submitted June 27, 2008 (with the exception of the above listed minor editorial revisions). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "SPL for approved supplement NDA 21-572/S-021."

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  
Suite 12B05  
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, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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/s/

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Sumathi Nambiar  
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