



NDA 21-572/S-057

SUPPLEMENT APPROVAL

Cubist Pharmaceuticals, LLC c/o Merck Sharp & Dohme Corp.
Attention: Sandra Lynn Wood, PhD
Director, Global Regulatory Affairs
351 North Sumneytown Pike
P.O. Box 1000, Mailstop UG-2C48
North Wales, PA 19454-2505

Dear Dr. Wood:

Please refer to your Supplemental New Drug Application (sNDA) dated March 1, 2017, received March 2, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cubicin (daptomycin for injection) 500 mg/vial.

This Prior Approval supplemental new drug application provides for labeling changes regarding the use of daptomycin in the pediatric population for *Staphylococcus aureus* bacteremia (SAB), based on the results of a trial in pediatric patients 1 to 17 years of age with SAB. This trial was conducted to fulfill the following Postmarketing Requirement listed in our November 19, 2015, letter:

- **804-7:** Conduct a multicenter, evaluator-blinded, randomized comparator study designed to evaluate the safety, efficacy and pharmacokinetics of IV daptomycin administered for up to 14 days in the treatment of pediatric patients ages 1 to 17 years with *S. aureus* bacteremia versus standard of care.

Specifically, the **HIGHLIGHTS, INDICATIONS AND USAGE (1), DOSAGE AND ADMINISTRATION (2), ADVERSE REACTIONS (6), Clinical Trials Experience (6.1)**, subsection, **USE IN SPECIFIC POPULATIONS (8), Pediatric Use (8.4)** subsection, **CLINICAL PHARMACOLOGY (12), Pharmacokinetics (12.3)** subsection, and **CLINICAL STUDIES (14)** sections of the U.S. package insert (PI) have been updated to reflect use in the pediatric population 1 to 17 years of age.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended and it is 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as 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 that include labeling changes 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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}

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

ENCLOSURE: Content of Labeling

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

/s/

SUMATHI NAMBIAR
09/01/2017