



NDA 21-572/S-046

SUPPLEMENT APPROVAL

Cubist Pharmaceuticals, Inc.
Attention: Jennifer Liscouski
Director, Regulatory Affairs
65 Hayden Avenue
Lexington, MA 02421

Dear Ms. Liscouski:

Please refer to your Supplemental New Drug Application (sNDA) dated May 28, 2014, received May 28, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CUBICIN (daptomycin for injection) Intravenous, 500 mg/vial.

We acknowledge receipt of your amendments dated August 14 and November 21, 2014. The changes to the carton and container labeling proposed in the August 14, 2014, amendment were not reviewed as part of this supplement and should be submitted as a new CMC supplement.

This "Prior Approval" supplemental new drug application provides for revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, WARNINGS AND PRECAUTIONS sections and the Pediatric Use subsection** regarding the potential for nervous system and muscular system effects in pediatric patients below 12 months of age. In addition, the **Nursing Mothers** and the **Animal Toxicology and/or Pharmacology subsections** of the package insert were revised based on the results of a 28-day intravenous neonatal dog study.

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 includes 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 Office of Antimicrobial Product
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
11/26/2014