



NDA 21-572/S-061

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-2CD48
North Wales, PA 19454-2505

Dear Dr. Wood:

Please refer to your Supplemental New Drug Application (sNDA) dated April 20, 2018, received April 20, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cubicin (daptomycin for injection), 500 mg/vial and Cubicin RF (daptomycin for injection), 500 mg/vial.

This “Changes Being Effected” supplemental new drug application provides for revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, ADVERSE REACTIONS (6)** section, **Post-Marketing Experience (6.2)** subsection, **CLINICAL PHARMACOLOGY (12)** section, **Microbiology (12.4)** subsection, and the **REFERENCES (15)** section, of the package inserts and minor editorial revisions.

More specifically, additional information related to “thrombocytopenia” and “platelet count” have been added to the prescribing information, in addition to revisions to the susceptibility test interpretive criteria, per the December 2017 FDA Guidance for Industry: “*Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs.*”

APPROVAL & LABELING

We have completed our review of this supplemental application 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling
- Cubicin
- Cubicin RF

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
12/03/2018