NDA 021572/S-065
NDA 021572/S-066

SUPPLEMENT APPROVALS

Cubist Pharmaceuticals, LLC
c/o Merck Sharp and Dohme, Inc.
Attention: Sandra L. Wood, PhD
Director, Global Regulatory Affairs
351 North Sumneytown Pike
Mailstop UG-2CD48
North Wales, PA 19454-2505

Dear Dr. Wood:

Please refer to your supplemental new drug applications (sNDAs) dated March 15, 2021, received March 15, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 021572/S-065 CUBICIN (daptomycin for injection)
- NDA 021572/S-066 CUBICIN RF (daptomycin for injection)

These "Changes Being Effected" sNDAs provide for revisions to the prescribing information (PI), **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection, to add information on toxic epidermal necrolysis (TEN). Additionally, the **WARNINGS AND PRECAUTIONS (5)** section has been revised to provide additional clarity on the development of drug-resistant bacteria, and the **PATIENT COUNSELING INFORMATION (17)** section has been revised to align it with the **ADVERSE REACTIONS (6)** section. Minor editorial revisions have been made throughout the PI.

APPROVAL & LABELING

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

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 FDA.gov.[1]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use, and Medication Guide), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE: Prescribing Information

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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
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