NDA 21572/S-063
NDA 21572/S-064

SUPPLEMENT APPROVAL

Cubist Pharmaceuticals, LLC
c/o Merck Sharp and Dohme, Inc
Attention: Casey Raudebush, MSN
Director, Global Regulatory Affairs
PO Box 1000, Mailstop UG-2C48
351 North Sumneytown Pike
North Wales, PA 19454-2505

Dear Ms. Raudenbush:

Please refer to your supplemental new drug applications (sNDAs) dated March 6, 2020, received March 6, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 021572/S-063 CUBICIN (daptomycin for injection)
NDA 021572/S-064 CUBICIN RF (daptomycin for injection)

These Prior Approval supplemental new drug applications provide for revisions to the **WARNINGS AND PRECAUTIONS** Section (5) of the prescribing information by adding subsections **(5.4) Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)** and **(5.5) Tubulointerstitial Nephritis (TIN)**. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and tubulointerstitial nephritis (TIN) are also added to the **ADVERSE REACTIONS** Section (6)**, (6.2) Post-Marketing Experience** subsection. In addition, minor editorial changes have been made throughout the prescribing information.

APPROVAL & LABELING

We have completed our review of these applications, as amended. 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] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, 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 labelings.

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 these NDAs, 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 these supplemental applications, 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) 796-1203.

Sincerely,

{See appended electronic signature page}

Dmirti Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[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
08/26/2020 05:45:54 AM