NDA 205435/S-013
NDA 205436/S-008

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Cubist Pharmaceuticals, LLC
c/o Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Attention: Casey Raudenbush, MSN
Director, Global Regulatory Affairs
351 North Sumneytown Pike, UG2D-68
North Wales, PA 19454

Dear Ms. Raudenbush:

Please refer to your supplemental new drug applications (sNDAs) dated June 30, 2020, received June 30, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 205435/S-013	SIVEXTRO (tedizolid phosphate) tablet, 200 mg
NDA 205436/S-008	SIVEXTRO (tedizolid phosphate) for injection, 200 mg

These Prior Approval sNDAs propose additions to the **Microbiology** (**12.4**) subsection to reflect the results of the 5-year US surveillance data of SIVEXTRO and susceptibility activity of organisms specific to the indication of Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

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

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

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 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 these 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 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT

Your June 30, 2020, submission contains the final report for the following postmarketing requirement (PMR) listed in the June 20, 2014 approval letter:

2159-6 Conduct US surveillance studies for five years from the date of marketing SIVEXTRO to determine if resistance to tedizolid has developed in those organisms specific to the indication in the label for ABSSSI.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are PMRs listed in the June 20, 2014 approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

If you have questions, call Deborah Kim, PharmD, RAC, Regulatory Project Manager, at (301) 796-9053.

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:

- Content of Labeling
    - Prescribing Information

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
10/22/2020 09:29:27 AM