

NDA 205435/S-011  
NDA 205436/S-006

## SUPPLEMENT APPROVALS

Cubist Pharmaceuticals, LLC  
c/o Merck Sharp & Dohme Corporation  
Attention: Neetesh Bhandari, BVSc, PhD, DABT  
Director, Global Regulatory Affairs  
351 Sumneytown Pike, PO Box 1000  
UG2CD-48  
North Wales, PA 19454-2505

Dear Dr. Bhandari:

Please refer to your supplemental new drug applications (sNDAs) dated March 22, 2019, received March 22, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 205435/S-011	SIVEXTRO (tedizolid phosphate) tablet, 200 mg
NDA 205436/S-006	SIVEXTRO (tedizolid phosphate) lyophilized powder for IV injection, 200 mg/mL

These Prior Approval supplemental new drug applications provide for revisions to the labeling to be in compliance with the requirements of the June 30, 2015, Pregnancy and Lactation Labeling Rule (PLLR). Specifically, updates have been made to Section 8, **USE IN SPECIFIC POPULATIONS**, Section 12, **CLINICAL PHARMACOLOGY**, Section 13, **NONCLINICAL TOXICOLOGY**, and to Section 17, **PATIENT COUNSELING 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.<sup>1</sup> 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 Effectuated” (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*.<sup>2</sup>

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 sNDAs, 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 questions, call Deborah Wang, PharmD, Regulatory Project Manager, at (301) 796-9053.

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:**

- Content of Labeling
  - Prescribing Information

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

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**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.**  
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/s/  
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