

NDA 205435/S-016
NDA 205436/S-013

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
REQUIREMENTS**

Cubist Pharmaceuticals LLC
c/o Merck Sharp & Dohme
Attention: Casey Raudenbush
Senior Director, Global Regulatory Affairs
351 North Sumneytown Pike, UG-3CD-54
North Wales, PA 19454-2505

Dear Casey Raudenbush:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 6, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER	SUPPLEMENT NUMBER	PRODUCT NAME
205435	S-016	Sivextro (tedizolid phosphate) tablet
205436	S-013	Sivextro (tedizolid phosphate) for injection

These Prior Approval sNDAs provide for the following expansions of use in the pediatric patient populations:

Supplement 016 provides for the expansion of the adult and adolescent indication for treatment of acute bacterial skin and skin structure infections (ABSSSI) to include pediatric patients <12 years of age and weighing ≥ 35 kg.

Supplement 013 provides for the expansion of the adult and adolescent indication for treatment of ABSSSI to include pediatric patients from (b) (4) to <12 years of age.

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 and Patient Package Insert), 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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 205435/S-016 and**

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>.

NDA 205436/S-013. Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Your deferred pediatric study required under section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81(b)(2)(vii). This required study is listed below.

4827-1 Complete development of the [REDACTED] (b) (4) formulation including product stability studies – long-term and accelerated storage, stress studies, and applicable in-use stability and compatibility.

Final Report Submission: 08/2025

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA)/biologics license application (BLA) or as a supplement to your approved NDA/BLA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated June 6, 2024, containing the final reports for the following postmarketing requirements listed in the June 20, 2014, approval letter (2159-5) and the January 29, 2018, post-approval postmarketing requirement letter (2159-7).

2159-5 Conduct a Phase 1 Single-Dose Safety and Pharmacokinetic Study of Oral and Intravenous Sivextro (tedizolid phosphate) in Inpatients Under 2 Years Old.

2159-7 Conduct a Randomized, Single Blind, Multicenter Safety and Efficacy Study of Intravenous to Oral Sivextro (tedizolid phosphate) and Intravenous to Oral Comparator for the Treatment of Acute

Bacterial Skin and Skin Structure Infections in Pediatric Patients
Aged Birth to <12 Years.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that postmarketing requirement 4827-1 listed in this approval letter is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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If you have any questions, email Joseph Nguyen, PharmD, Regulatory Project Manager, at Joseph.Nguyen@fda.hhs.gov or call (301) 348-3937.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
- Carton and Container Labeling

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/

PETER W KIM
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