NDA 22-110/S-015

SUPPLEMENT APPROVAL

Cumberland Pharmaceuticals, Inc.
Attention: Beth A. Zaborny
Director, Regulatory Affairs
2525 West End Avenue, Suite 950
Nashville, TN 37203

Dear Ms. Zaborny,

Please refer to your supplemental new drug application (sNDA), and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vibativ (telavancin hydrochloride) Injection, 750 mg.

This Prior Approval supplemental new drug application, submitted in response to the Agency's December 11, 2018 letter, provides for updates to multiple sections of the Vibativ package insert and patient Medication Guide to comply with the Pregnancy and Lactation Labeling Rule (PLLR).

In addition, the **CLINICAL PHARMACOLOGY (12)** section, **Microbiology (12.4)** subsection of the prescribing information has been updated to remove the susceptibility test interpretive criteria and related information from the approved labeling in accordance with the requirements of Section 3044 of the 21st Century Cures Act that added Section 511A(d)(1) of the FD&C Act, Revisions have also been made to the **HOW SUPPLIED/STORAGE AND HANDLING (16.0)** section, and carton and immediate container labeling to update the terminology of "single-use" to "single-dose."

APPROVAL & LABELING

We have completed our review of this application, as amended and it is 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 Package Insert 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).

CARTON AND CONTAINER LABELING

We acknowledge your December 13, 2019 submission containing final printed 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 22-110/S-015**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- 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/

DMITRI IARIKOV
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