

NDA 50-587/S-083

## SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp,  
a subsidiary of Merck & Co, Inc.  
Attention: Carol A. Ruffing  
Principal Scientist, Global Regulatory Affairs  
351 N Summneytown Pike  
PO Box 1000 UG2C-50  
North Wales, PA 19454-2595

Dear Ms. Ruffing:

Please refer to your supplemental new drug application (sNDA) dated and received May 6, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Primaxin IV (imipenem and cilastatin sodium).

This “Changes Being Effected” sNDA provides for the inclusion of sodium bicarbonate as the buffering agent in the **DESCRIPTION (11)** section of the prescribing information (PI). In addition, “cilastatin sodium” has been changed to “cilastatin (free acid equivalent)” in the **HIGHLIGHTS (HL), DOSAGE FORMS AND STRENGTHS (3),** and **HOW SUPPLIED (16)** sections. “*Clostridium difficile*” has been changed to “*Clostridioides Difficile*” in the following sections and subsections, **HIGHLIGHTS (HL), FULL PRESCRIBING INFORMATION CONTENTS , ADVERSE REACTIONS (6)** and *Clostridioides Difficile*- Associated Diarrhea (5.4.) along with minor editorial revisions throughout the (PI).

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is 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

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

Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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 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 50-587/S-083.**” Approval of this submission by FDA is not required before the labeling is used.

### **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 Christopher Smith, Regulatory Project Manager, at 301-796-4851.

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<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>.

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarkov, 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
- Carton and Container Labeling

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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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DMITRI IARIKOV  
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