



NDA 021337/S-048

## **SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.  
Attention: Brian Wing  
Senior Scientist, Regulatory Liaison, Global Regulatory Affairs  
351 North Sumneytown Pike  
P.O. Box 1000, UG2D  
North Wales, PA 19454-2505

Dear Mr. Wing:

Please refer to your supplemental new drug application (sNDA) dated June 04, 2019, received June 04, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INVANZ (ertapenem for injection), 1 g.

This “Changes Being Effectuated” supplemental new drug application provides for revisions to the prescribing information, **ADVERSE REACTIONS** (6) section, **Post-Marketing Experience** (6.2) subsection, under the **Skin and Subcutaneous Tissue Disorders** heading, to include the adverse reaction term “Acute Generalized Exanthematous Pustulosis (AGEP).”

### **APPROVAL & LABELING**

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed 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.

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

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).

### **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 Jacquelyn Rosenberger, PharmD, RAC, Regulatory Project Manager, at (301) 796-9179.

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>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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DMITRI IARIKOV  
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