NDA 202106/S-007

SUPPLEMENT APPROVAL

B. Braun Medical Inc.
Attention: Cindy Katsempris
Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Katsempris:

Please refer to your supplemental new drug application (sNDA) dated September 18, 2019, received September 19, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container, 500 mg and 1 g.

This supplemental application provides for the following revisions to the prescribing information:

PRESCRIBING INFORMATION

(1) Addition of a **Severe Cutaneous Adverse Reactions (5.2)** subsection to the **WARNINGS AND PRECAUTIONS (5)** section.
(2) Reference to Severe Cutaneous Adverse Reactions has been added to the **ADVERSE REACTIONS (6)** section, and additional information added to the Post-Marketing Experience (6.2) subsection, under Skin and Subcutaneous Disorders.
(3) Updates the **CLINICAL PHARMACOLOGY (12)** section, to add a **Pharmacodynamics (12.2)** subsection, and revises the **Pharmacokinetics (12.3)** subsection, to provide information on plasma concentrations and product elimination.
(4) Updates the **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection, **Specific Populations**, **Pediatric Patients** section, to provide pharmacokinetic parameters in patients less than 3 months of age.

Additionally, editorial revisions have been made in the **REFERENCES (15)** section and throughout labeling.

CARTON

The carton has been revised to include a “Discard unused portion” statement and the word “single use” has been revised to read “single-dose”.

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.[1] 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 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 LABELING

We acknowledge your January 30, 2020, submission containing final printed carton labeling.

[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 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-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton 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
05/12/2020 11:52:00 AM