DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202106/S-003

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 February 28, 2017, received March 2, 2017, and your amendment, 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, 0.5 g and 1 g.

This Prior Approval supplemental new drug application provides for the following:

(1) Changes to the **DOSAGE AND ADMINISTRATION** section, **Use in Adult Patients with Renal Impairment (2.2)** subsection, **WARNINGS AND PRECAUTIONS** section to re-organize the list, and the **ADVERSE REACTIONS** section, **Post-Marketing Experience** (6.2) subsection to include drug rash with eosinophilia and systemic symptom (DRESS) syndrome.
(2) Updates to the PI based on requirements of the Pregnancy and Lactation Labeling Rule (PLLR).
(3) Updates to the PI based on recent changes to the labeling of the Reference Listed Drug.
(4) Editorial revisions throughout labeling.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 Maureen Dillon-Parker, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director (Acting)
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DMITRI IARIKOV
01/19/2018