NDA 050796/S-30

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 and received October 28, 2021, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ceftriaxone for Injection and Dextrose Injection in the Duplex Container, 1 g and 2 g.

We also refer to our letter dated September 30, 2021, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for ceftriaxone. This information pertains to the risk of neurotoxicity including seizures and encephalopathy that may be increased in patients with renal insufficiency.

This supplemental new drug application provides for revisions to the labeling for Ceftriaxone for Injection and Dextrose Injection in the Duplex Container consistent with our September 30, 2021 letter.

The **WARNINGS AND PRECAUTIONS (5)** section, **Neurological Adverse Reactions (5.3)** subsection was revised to state that serious neurological adverse reactions including seizures and encephalopathy that may be increased in patients with renal impairment have been reported during postmarketing surveillance with ceftriaxone and, appropriate dosage adjustments are needed in patients with severe renal impairment.

Edits to reflect this change are also included in the following sections of the attached Prescribing Information (PI): the **HIGHLIGHTS OF PRESCRIBING INFORMATION,** the **ADVERSE REACTIONS (6)** section**, Postmarketing Experience (6.2)** subsection, **OVERDOSAGE (10)** section, and **PATIENT COUNSELING INFORMATION (17).**

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).

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

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

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

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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