NDA 050779/S-027

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

B. Braun Medical, Inc.
Attention: Cindy Katsempris
Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109-9341

Dear Ms. Katsempris:

Please refer to your supplemental new drug application (sNDA) dated January 21, 2020, received January 28, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Cefazolin for Injection USP and Dextrose Injection USP in the Duplex Container, 1 g and 2 g.

This Prior Approval supplemental application proposes revisions to the prescribing information based on the results of the pediatric study listed as a postmarketing requirement (PMR) in the January 13, 2012 approval letter for Supplement S-018.

Accordingly, revisions were made to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, **INDICATIONS AND USAGE (1)**, **DOSAGE AND ADMINISTRATION (2)**, **ADVERSE REACTIONS (6)**, **USE IN SPECIFIC POPULATIONS (8)**, **OVERDOSAGE (10)**, and **CLINICAL PHARMACOLOGY (12)** sections of the prescribing information.

APPROVAL & LABELING

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

[1] 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*.[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).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated January 21, 2020, containing the final report for the following PMR listed in the January 13, 2012, approval letter:

1869-2: A safety study in 100 pediatric patients, ages 10-17 years, of single dose cefazolin preoperative prophylaxis using the dose equivalent to 2 gram adult exposure (as determined in the PK study) in pediatric patients.

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes all of your postmarketing requirements acknowledged in our January 13, 2012 approval letter.

REPORTING REQUIREMENTS

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

[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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE: 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/

SUMATHI NAMBIAR
11/23/2020 02:35:08 PM