



NDA 50-779/S-025

**SUPPLEMENT APPROVAL**

B. Braun Medical, Inc.  
Attention: Rebecca A. Stolarick  
Corporate Vice President, Regulatory Affairs  
901 Marcon Boulevard  
Allentown, PA 18109

Dear Ms. Stolarick:

Please refer to your Supplemental New Drug Application (sNDA) dated September 10, 2015, received September 10, 2015, submitted under 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, 1g and 2g, Intravenous.

We also acknowledge receipt of your amendment dated September 30, 2015.

This "Prior Approval" supplemental new drug application, submitted in response to the Division's August 10, 2015, supplement request letter, provides for updates to the package insert, **DOSAGE AND ADMINISTRATION** section (2), Dosage in Pediatric Patients (2.3) and **USE IN SPECIFIC POPULATIONS** section (8), Pediatric Use (8.4) to provide information on pediatric dosing. In addition, revisions have been made to the **CLINICAL PHARMACOLOGY** section (12), **Microbiology** subsection (12.4), of the package insert to update the *in vitro* susceptibility test interpretive criteria (breakpoints), quality control ranges and to the **REFERENCES** section.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below:

- Addition of the statement: "The disk diffusion interpretive criteria are provided in Table 4" as the last sentence of the paragraph under "Diffusion Techniques" in subsection 12.4.

**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 (which includes the revision listed above) 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 with the revisions indicated above 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 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-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
10/08/2015

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