DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-796/S-017

SUPPLEMENT APPROVAL

B. Braun Medical, Inc.
Attention: Rebecca 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 March 25, 2013, received March 25, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ceftriaxone for Injection and Dextrose Injection in the Duplex Container, 1g and 2g.

This "Changes Being Effected" supplemental new drug application provides for the following:

1. Revisions to the Recommended Dosing Schedule table in **"HIGHLIGHTS OF PRESCRIBING INFORMATION"** and to Table 1 in the **DOSAGE AND ADMINISTRATION** Section (2.1), replacing "twice a day" with "every 12 hours".

2. Editorial revisions to Table 6 – "Susceptibility Interpretive Criteria for Ceftriaxone" in the **Microbiology** Section 12.4, to replace column heading titles "Susceptible", "Intermediate" and "Resistant" with the abbreviations "S", "I" and "R.

We have completed our review of this supplemental application 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 revisions listed below:

- Remove the parentheses around the abbreviations "S", "I" and "R" in Table 6.

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, with the minor editorial revisions noted 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 listed **or** 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
Deputy Director for Safety
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/

SUMATHI NAMBIAR
04/10/2013