DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-796/S-011

SUPPLEMENT APPROVAL

B. Braun Medical, Inc.
Attention: Rebecca A. Stolarik
Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Stolarik:

Please refer to your Supplemental New Drug Application (sNDA) dated October 30, 2008, received October 31, 2008, 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.

We also refer to our approval letter dated January 13, 2012, which contained the following error:

- An incorrect version of the Content of Labeling was included as an enclosure.

This replacement approval letter incorporates the corrected version of the Content of Labeling. The effective approval date will remain January 13, 2012, the date of the original approval letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY, PRECAUTIONS, ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATIONS** sections of the product labeling to make these sections consistent with corresponding sections in the product labeling for the reference listed drug (RLD), Rocephin.

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.

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 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from 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 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}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S): 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/

KATHERINE A LAESSIG
01/13/2012