DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-796/S-012

SUPPLEMENT APPROVAL

B. Braun Medical, Inc.
Attention: Susan Olinger, J.D.
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your Supplemental New Drug Application (sNDA) dated September 1, 2009, received September 4, 2009, 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, 1g and 2g.

We also acknowledge receipt of your amendment dated June 22, 2010.

This "Changes Being Effected" supplemental new drug application provides for revisions, including new information in the **CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS,** and **ADVERSE REACTIONS** sections to further clarify the use of Ceftriaxone for Injection and Dextrose Injection in the Duplex® Container with other solutions or products, and to update the labeling so that it is consistent with the reference listed drug (RLD), Rocephin®.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50796	SUPPL-12	B BRAUN MEDICAL INC	CEFTRIAXON SODIUM/DEXTROSE INJECTION 1G/

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
06/25/2010