DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-796/S-007
50-796/S-008

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

Dear Ms. Olinger:

Please refer to your supplemental new drug application(s) dated August 27, 2007, received August 27, 2007 for NDA 50-796/S-007 and November 27, 2007, received November 28, 2007 for NDA 50-796/S-008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceftriaxone for Injection and Dextrose Injection in the Duplex® Container.

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for the following:

- **SLR-007** provides for new safety information (in the **CONTRAINDICATIONS**, **WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS** sections) as a result of a June 2007 MedWatch Alert regarding adverse events reported during the postmarketing use of the reference listed drug (RLD), Rocephin®. The MedWatch alert addressed the potential risk associated with concomitant use of ceftriaxone with calcium-containing solutions or products.

- **SLR-008** provides for new safety information in the **CONTRAINDICATIONS** ***(Neonates (≤ 28 days)),*** **WARNINGS** ***(Hypersensitivity, Interaction with Calcium-Containing Products and Clostridium difficile*** **as new headers)**, and **ADVERSE REACTIONS** sections as a result of a September 2007 MedWatch alert. These updated revisions further clarify the potential life-threatening and fatal risk to neonates associated with the use of Ceftriaxone for Injection regarding adverse events reported during the postmarketing use of the RLD, Rocephin®.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on November 27, 2007.

We note that your November 27, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling submitted November 27, 2007

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathrine Laessig
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