DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-779/S-011

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 dated January 16, 2007, received January 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cefazolin for Injection, USP and Dextrose Injection, USP in the Duplex® Container.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We also acknowledge receipt of your submission dated April 30, 2008, which constituted a complete response to our action letter dated March 11, 2008.

This supplemental new drug application provides for the following:

- Updating the container package insert for Cefazolin for Injection, USP and Dextrose Injection, USP in the Duplex® Container, such that the microbiology section of the package insert matches that of the reference listed drug (RLD), Ancef.

- Updates to the **Indications and Usage**, **Pediatric Dosage**, and **References** sections to match the RLD.

We completed our review of this application and it is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text. As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed label submitted April 30, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "SPL for approved supplement NDA 50-779/S-011."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling dated April 30, 2008

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
10/31/2008 01:58:29 PM