NDA 50-779

B. Braun Medical Inc.
Attention: John G. D'Angelo, M.S., R.Ph.
Corporate Vice President
2525 McGaw Avenue
P.O. Box 19791
Irvine, CA 92623

Dear Mr. D'Angelo:

Please refer to your new drug application (NDA) dated August 23, 1999, received August 25, 1999, 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, 500 mg cefazolin or 1 gram cefazolin in 50 mL Dextrose Injection . We note that 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 acknowledge receipt of your submissions dated October 27, 1999, January 19, 2000, February 2, 2000, May 12, 2000, May 19, 2000, and July 20, 2000.

This new drug application provides for the use of Cefazolin for Injection USP and Dextrose Injection USP for the treatment of respiratory tract infections, urinary tract infections, skin and skin structure infections, biliary tract infections, bone and joint infections, genital infections, septicemia, endocarditis, and perioperative prophylaxis.

We have completed the review of this application as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and immediate container labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 50-779." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement at this time.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Beth Duvall-Miller, B.S., Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure