CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-780

Trade Name: Cefuroxime for Injection USP and Dextrose Injection USP in the Duplex Container, 750 mg cefuroxime or 1.5 g cefuroxime in 50mL Dextrose Injection

Generic Name: cefuroxime

Sponsor: B. Braun Medical Inc.

Approval Date: February 21, 2001

Indications: For the treament of lower respiratory tract infections, urinary tract infections, skin and skin structure infections, Septicemia, meningitis, gonerrhea, and bone and joint infections.

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-780

B. Braun Medical Inc.
Attention: John G. D'Angelo, M.S., R.Ph.
Corporate Vice President, Regulatory and Medical Affairs
2525 McGaw Avenue
P.O. Box 19791
Irvine, CA 92623-9791

Dear Mr. D'Angelo:

Please refer to your new drug application (NDA) dated April 17, 2000, received April 21, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cefuroxime for Injection USP and Dextrose Injection USP in the DUPLEX™ Container, 750 mg cefuroxime or 1.5 g cefuroxime in 50 mL Dextrose Injection.

We acknowledge receipt of your submissions dated May 22, 2000; December 21, 2000; February 12, 2001; and February 16, 2001.

This new drug application provides for the use of Cefuroxime for Injection USP and Dextrose Injection USP for the treatment of lower respiratory tract infections, urinary tract infections, skin and skin structure infections, septicemia, meningitis, gonorrhea, and bone and joint infections.

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). 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 50-780." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submissions dated December 21, 2000, and February 12, 2001. These commitments are listed below.

1. Implement an impurity specification of < 0.75% for the cefuroxime anti-isomer.

2. Provide updated stability data to support an 18-month shelf-life and the overage analysis prior to commercialization of Cefuroxime for Injection USP and Dextrose Injection USP in the DUPLEX™ Container.

3. Identify all impurities found greater than 0.1% (expressed as percent of the active chromatographic peak area).

Submit chemistry, manufacturing, and controls data to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, and any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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

Please note, if you choose to use a proprietary name for this product, the name and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure