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*APPLICATION NUMBER:*

**50-679/S-007**

# APPROVAL LETTER

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**NDA 50-679/S-007**

JAN 27 1999

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attention: Hugh McIlhenny, Ph.D.
Director, Worldwide Regulatory Affairs
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Dr. McIlhenny:

Please refer to your supplemental new drug application dated December 23, 1996, received December 23, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxipime® (cefepime hydrochloride) for 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 May 16, 1997, August 6, 1997, October 31, 1997, November 20, 1997, December 4, 1997, November 24, 1998, and January 25, 1999.

This supplemental new drug application provides for:

1. The addition of pharmacokinetic information for pediatric patients under the **Special Populations** subsection of the **CLINICAL PHARMACOLOGY** section of the labeling.
2. A revised **Pediatric Use** subsection in the **PRECAUTIONS** section of the labeling that includes statements on the safety and effectiveness of cefepime in the treatment of pediatric patients (2 months up to 16 years) with uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, pneumonia, and as empiric therapy for febrile neutropenic patients.
3. The addition of pediatric dosing information in Table 13 of the **DOSAGE AND ADMINISTRATION** section of the labeling.
4. The addition of a statement recommending adjusted dosage for pediatric patients with impaired renal function in the **DOSAGE AND ADMINISTRATION** section of the labeling.

We have completed the review of this supplemental 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 enclosed labeling text. Accordingly, the supplemental 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).

Please submit 20 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-679/S-007." Approval of this submission by FDA is not required before the labeling is used.

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 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, contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

/S/

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

Enclosure