DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-679/S-009, S-014 and S-018

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Michael Brady, Ph.D.
Director, Regulatory Science
5 Research Parkway - P.O. Box 5100
Wallingford, CT 06492-7660

Dear Dr. Brady:

Please refer to your supplemental new drug applications dated November 19, 1997 (S-009), June 18, 1999 (S-014), and September 15, 2000 (S-018), received November 20, 1997, June 21, 1999, and September 18, 2000, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxipime® (cefepime hydrochloride) for Injection. We note that these applications are 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 January 19, 1998 (S-009), October 7, 1999 (S-014), February 8, 2000 (S-014), January 9, 2002 (S-009, S-014, and S-018) and May 13, 2002 (S-009, S-014 and S-018). We also note the Agency's facsimile to you dated October 1, 2001. Your submissions of January 9, 2002 and May 13, 2002, constituted complete responses to our June 1, 2001 action letter for NDA 50-679/S-009 and our March 22, 2002 action letter for NDA 50-679/S-009, S-014 and S-018.

These supplements propose the following changes:

NDA 50-679/S-009:

1. Addition of myoclonus and seizures in renally impaired patients with unadjusted dosages of cefepime to the **ADVERSE REACTIONS, Postmarketing Experience** section;
2. Addition of statements to the **PRECAUTIONS** and **OVERDOSAGE** sections regarding the need to adjust the dosage in patients with renal insufficiency;

NDA 50-679/S-014:

3. Addition of updated language to the **PRECAUTIONS, Geriatric Use** section, in accordance with the Final Rule entitled "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs: Addition of 'Geriatric Use' Subsection in the Labeling".

NDA 50-679/S-018:

4. Addition of neurologic adverse events to the **PRECAUTIONS**, **ADVERSE REACTIONS**, **Postmarketing Experienc**e, and **OVERDOSAGE** sections.

We have completed the review of these supplemental applications 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 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 (package insert submitted May 13, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, these submissions should be designated "FPL for approved supplement NDA 50-679/S-009, S-014 and S-018." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, call LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Janice Soreth

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