NDA 50-632/S-010

Bristol-Myers Squibb Company
Attention: Joseph A. Linkewich, Pharm.D.
P.O. Box 4000
Princeton, New Jersey 08543-4000

Dear Dr. Linkewich:

Please refer to your supplemental new drug application dated December 19, 1997, received December 29, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azactam (aztreonam injection).

We acknowledge receipt of your submission dated April 20, 1998.

This supplemental new drug application provides for the addition of pediatric use statements in the Azactam (aztreonam injection) package insert in which the following sections and subsections are changed: CLINICAL PHARMACOLOGY; PRECAUTIONS, Pediatric Use; ADVERSE REACTIONS, Pediatric Adverse Reactions; and DOSAGE AND ADMINISTRATION. In addition, the package insert has been updated in the CLINICAL PHARMACOLOGY, Microbiology subsection and has been revised by editorial changes.

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 submitted labeling (package insert submitted April 20, 1998) with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. Serial commas should be inserted throughout the text.

2. In the DESCRIPTION section:

   In the chemical name, delete the hyphen between "(2S,-3S)."

3. In the CLINICAL PHARMACOLOGY section:

   a. In the first sentence of the first paragraph, insert "aztreonam" between "produced" and "peak."
   b. In the third paragraph, give the full name for "*H.*" i.e., "*Haemophilus*"; add a hyphen between "eight hour"; give the full name for "*Ps.*" i.e., "*Pseudomonas*"; and add a hyphen between "2 g."
   c. In the first sentence of the fourth paragraph, "When aztreonam pharmacokinetics were

assessed . . . to be comparable (down to 9 months old).” add a hyphen between “9 months.”

d. In the sixth paragraph, add a period after “prolonged”; capitalize the “S” in “see”; add a period after “Patients”; and delete the period after the parenthesis. That is, “. . . prolonged. (See DOSAGE AND ADMINISTRATION, Renal Impairment in Adult Patients.) The serum . . . .”
e. In the seventh paragraph, add a hyphen between “1 g” and “2 g” and after “8” and “12.”
f. In the eleventh paragraph, change “breast milk” to “human milk.”

4. In the WARNINGS section:

   In the fifth paragraph, do not capitalize or italicize “*Clostridia*.”

5. In the PRECAUTIONS section:

   In the Nursing Mothers subsection, change “breast milk” to “human milk.”

6. In the ADVERSE REACTIONS section:

   Delete all periods placed at the end of the adverse reactions.

These revisions are terms of the approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

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 50-632/S-010.” 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, 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, contact Mr. Stephen T. Trostle, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

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