DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-580/S-040
NDA 50-632/S-013

Bristol-Myers Squibb Company
Attention: Lori A. DeVore
Associate Director, Global Regulatory Strategy
5 Research Parkway
Signature 91 Building, 3SIG-511
Wallingford, CT 06492

Dear Ms. DeVore:

Please refer to your supplemental new drug applications dated March 12, 2007, received March 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azactam® (aztreonam) Injection (NDA 50-580), and Azactam® (aztreonam injection) in GALAXY Plastic Container (PL 2040) for Intravenous Use (NDA 50-632). These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug application revises the WARNINGS PRECAUTIONS, information for patients section to include new information for *Clostridium difficile* associated disease (CDAD).

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplements NDA 50-580/S-040, NDA 50-632/S-013**." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to the NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-1400.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
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/

Kathrine Laessig
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