



NDA 50-580/S-037
NDA 50-632/S-012

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, New Opportunities and Product Development
Global Regulatory Strategy
P.O. Box 4000
Princeton, New Jersey 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated April 19, 2004 (S-037) and April 21, 2004 (S-012), received May 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azactam[®] (aztreonam for injection, USP) (NDA 50-580), and Azactam[®] (aztreonam injection) (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.

We acknowledge receipt of your submissions dated November 1, 2004.

These supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter.

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 these NDAs 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Susmita Samanta, M.D., Regulatory 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
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/s/

Janice Soreth
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