



NDA 50-679/S-024

Bristol-Myers Squibb Company
Attention: E. Kwame Obeng, PhD
Director-Global Regulatory Science-CMC
P.O. Box 5400
Princeton, NJ 08543-5400

Dear Dr. Obeng:

Please refer to your supplemental new drug application dated March 8, 2005, received March 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MAXIPIME® (cefepime hydrochloride) Injection, 500 mg, 1g, and 2g/vial. 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 also acknowledge receipt of your submission dated September 23, 2005, received September 29, 2005. This submission constituted a complete response to our August 31, 2005 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provide for process modifications,

We completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter. However, address the following issues:

1. The acceptance criteria for N-methylpyrrolidine is listed with the stability data as which is considerably higher than the data justified. Revise this consistent with the data and provide this information in the next annual report.
2. The acceptance limits for the assay on page 11 in the submission is different than that of the remaining batches. Correct this in the annual report.

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

If you have any questions, call J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

James D. Vidra, PhD
Chemistry Team Leader
Division of Anti-Infective and Ophthalmology Products
DNDC III, Office of New Drug Chemistry
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/

Jim Vidra
3/8/2006 10:06:52 AM