DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-706/S-023

AstraZeneca
Attention: Julie Nelson
Labeling Manager, Regulatory Affairs
1800 Concord Pike
P.O.Box 8355
Wilmington, DE 19803-8355

Dear Ms. Nelson:

Please refer to your supplemental new drug application dated March 26, 2007, received March 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MERREM® IV (meropenem for injection). 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 acknowledge receipt of your submissions dated December 12, 2007 and March 12, 2008. Your submission of December 12, 2007 constituted a complete response to our September 25, 2007 action letter.

This "Changes Being Effected" supplemental new drug application provides for changes to the WARNINGS and ADVERSE REACTIONS section, based on the post-marketing experiences.

We completed our review of this application, as amended. This application is 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 (package insert submitted March 12, 2008).

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 supplement NDA 50-706/S-023**" Approval of this submission 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

3/13/2008 11:52:38 AM