DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-706/S-025 **APPROVAL LETTER**

AstraZeneca Pharmaceuticals LP
Attention: Darci L. Bertelsen
Regulatory Affairs Director
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19850-8355

Dear Ms. Bertelsen:

Please refer to your supplemental new drug application dated July 23, 2009, received July 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MERREM® I.V. (meropenem for injection).

This "Changes Being Effected" supplemental new drug application provides for revised **WARNINGS** and **PRECAUTIONS** sections to include valproic acid interaction information.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, submitted on July 23, 2009.

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 50-706/S-025**."

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

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 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, please contact Susmita Samanta, M.D., Regulatory Project Manager, at 301-796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research