DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050706/S-032
NDA 050706/S-034

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals LP
Attention: Cynthia S. Dommisse, Pharm.D.
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Dommisse:

Please refer to your Supplemental New Drug Applications (sNDA), S-032 dated and received February 28, 2013, and S-034, dated and received July 18, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MERREM I.V. (meropenem for injection)

We acknowledge receipt of your amendments dated April 10 and November 14, 2013 for S-032, and December 3, 2013 for S-034.

S-032: This "Prior Approval" labeling supplement provides for revisions to Section 2**, DOSAGE AND ADMINISTRATION,** regarding adult and pediatric dosing information for the treatment of complicated skin and skin structure infections due to *Pseudomonas aeruginosa*, and Section 12**, CLINICAL PHARMACOLOGY,** Subsection 12.4**, Microbiology**, regarding susceptibility interpretive criteria for *P. aeruginosa.*

S-034: This "Changes Being Effected" labeling supplement updates Section 2**, DOSAGE AND ADMINISTRATION,** Subsection 2.6**, Stability and Storage**, and Section 8**, USE IN SPECIFIC POPULATIONS,** Subsection 8.3, **Nursing Mothers.**

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
12/16/2013