DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50706/S-035

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals, LP
Attention: Cynthia S. Dommisse
Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Dommisse:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 20, 2014, 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 amendment dated December 19, 2014.

This "Prior Approval" supplemental new drug application provides for labeling revisions based on the results of a study conducted by the National Institutes of Health (NIH) in pediatric patients less than 3 months of age as indicated below:

HIGHLIGHTS OF PRESCRIBING INFORMATION

RECENT MAJOR CHANGES

- Addition of Indications and Usage, Intra-Abdominal Infections, Pediatric Patients (less than 3 months of age) (1.2)
- Addition of Dosage and Administration, Use in Pediatric Patients (less than 3 months of age (2.3)
- Deletion of Dosage and Administration, Adult Patients (2.1)
- Deletion of Stability and Storage (2.6)

INDICATIONS AND USAGE

- Revised age group for complicated intra-abdominal infections to include all pediatric patients

DOSAGE AND ADMINSTRATION

- Added information regarding dosing for pediatric patients less than 3 months of age with complicated intra-abdominal infections

FULL PRESCRIBING INFORMATION

- **INDICATIONS AND USAGE** section, **Intra-Abdominal Infections** subsection (**1.2**): revised to include pediatric patients
- **DOSAGE AND ADMINSTRATION** section, **Use in Pediatric Patients** subsection (**2.3**): addition of information regarding dosing for pediatric patients less than 3 months of age with complicated intra-abdominal infections
- **ADVERSE REACTIONS s**ection, **Adverse Reactions from Clinical Trials** subsection (**6.1**): revisions to adverse reactions in pediatric patients and addition of information from the pediatric study
- **USE IN SPECIFIC POPULATIONS** section, **Pediatric Use** subsection (**8.4**):addition of pediatric patients less than 3 months of age with complicated intra-abdominal infections
- **CLINICAL PHARMACOLOGY** section**, Pharmacokinetics (12.3), Pediatric Patients** subsection: addition of information regarding meropenem pharmacokinetic parameters in patients less than 3 months of age

APPROVAL & LABELING

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

CONTENT OF LABELING

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(S):
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
12/19/2014