



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-706/S-016

AstraZeneca LP
Attention: Nicholas J. Troise
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Troise:

Please refer to your supplemental new drug application dated February 3, 2004, received February 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MERREM[®] IV (meropenem for injection). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to comply with the FDA's Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use (21 CFR Part 201)", published on February 6, 2003 (68 FR 6062).

We completed our review of this supplemental application and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted February 3, 2004 (package insert Rev 01/04 SIC 64211-00).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-706/S-016." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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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 Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products (HFD-520)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth
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