DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-068/S-016

AstraZeneca
Attn: Nicholas Troise, Director, Regulatory Affairs
PO Box 8355
1800 Concord Pike
Wilmington, DE 19803-8355

Dear Mr. Troise:

Please refer to your supplemental new drug application dated February 15, 2006, received February 16, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FOSCAVIR® (foscarnet sodium) Injection.

This "Changes Being Effected" supplemental new drug application provides for changes to the OVERDOSAGE section of the package insert to include updates from post-marketing reports.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 15, 2006.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call David Araojo, Pharm.D, Regulatory Project Manager, at (301) 796-0669.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Approved label

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

/s/

Jeffrey Murray

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