DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-363/ S-034

PRIOR APPROVAL SUPPLEMENT

Novartis Pharmaceuticals Corporation
Attention: Dr. John R. Cutt
Vice President, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Cutt:

Please refer to your supplemental new drug application dated January 17, 2008, received January 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FAMVIR® (famciclovir) Tablets 125 mg, 250 mg and 500 mg.

We acknowledge receipt of your submissions dated:

May 21, 2008	July 11, 2008	July 15, 2008	September 26, 2008	November 26, 2008

This supplemental new drug application provides for:

Revisions to the U.S. Package Insert to provide updates to the CLINICAL PHARMACOLOGY, PRECAUTIONS and ADVERSE REACTIONS sections of the label.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) agreed-upon on December 15, 2008.

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling agreed-upon on December 15, 2008. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Antiviral Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Paras M. Patel, Regulatory Project Manager, at (301) 796-0783.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (Label)

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

/s/

Debra Birnkrant
12/22/2008 01:46:31 PM
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