DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-363/SLR-026

Novartis Pharmaceuticals Corporation
Attention: Sheila Mathias, Pharm.D.
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Mathias:

Please refer to your supplemental new drug application dated August 24, 2005, received August 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Famvir® (famciclovir) Tablets (125mg, 250 mg, and 500 mg).

We acknowledge receipt of your submission dated August 24, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the PRECAUTIONS, General, PRECAUTIONS, Information for Patients subsections of the package insert, and the addition of a Post Marketing Experience, ADVERSE REACTION subsection.

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 and with the minor editorial revisions listed below.

- Please delete the "n" number information from the bottom row of Table 3.

- Under PRECAUTIONS, General, change "glactose" to "galactose."

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-363/SLR-026**." Approval of this submission by FDA is not required before the labeling is used.

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 Karen Winestock, Regulatory Project Manager, at (301) 796-0834.

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

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
2/22/2006 04:49:18 PM
NDA 20-363