DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-363/S-027
NDA 20-363/S-028

Novartis Pharmaceuticals Corporation
Attn: Sheila A. Mathias, Ph.D., Senior Associate Director
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Mathias:

Please refer to your new drug applications (NDA) dated October 14, 2005 and November 11, 2005, received October 17, 2005 and November 14, 2005 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Famvir® (famciclovir) tablets.

We acknowledge receipt of your submissions dated.

November 16, 2005	March 22, 2006	July 21, 2006
January 13, 2006	April 17, 2006	
February 17, 2006	July 6, 2006	
March 17, 2006	July 14, 2006	

These supplemental new drug applications provide for the use of Famvir® (famciclovir) tablets for:

- New dosing recommendation (S027) for the treatment of recurrent genital herpes in immunocompentent patients, specifically a reduction in course of therapy from famciclovir 125 mg bid for 5 days to 1000 mg bid for 1 day
- New indication (S028) for the treatment of recurrent herpes labialis (cold sores) in immunocompetant patients with a single dose of famciclovir 1500 mg.

We completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text to include the minor editorial revisions as discussed in the July 27, 2006, teleconference.

The final printed labeling (FPL) must be identical to the enclosed labeling, and include the agreed-upon minor editorial revision as outlined in the July 27, 2006 teleconference. These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product labeling may render the product misbranded and an unapproved new drug.

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 these

submissions "**FPL for approved NDA 20-363/S-027 and NDA 20-363/S-028**." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 1 month to <18 years until June 30, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

> Description of Commitment: **Deferred pediatric study under PREA for the treatment of HSV or VZV infection and/or suppressive therapy for HSV in pediatric patients ages 1 month to <18 years of age.**
>
> Final Report Submission: June 30, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

We remind you of your postmarketing study commitment in your submission dated July 6, 2006. This commitment is listed below.

> Description of Commitment: **Conduct a study to investigate the treatment effect of famciclovir single-day therapy in Blacks with recurrent herpes infection.**
>
> | | |
> |---|---|
> | Protocol Submission: | by 09/2006 |
> | Study Start: | by 03/2007 |
> | Final Report Submission: | by 09/2009 |

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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

If you have any questions, call Paras Patel, R.Ph.,, 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: approved draft labeling

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
7/28/2006 11:44:08 AM
NDA 20-363