DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-629/S-008

Novartis Consumer Health, Inc
Attention: Cynthia Psaras
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Dr. Psaras:

Please refer to your supplemental new drug application dated December 10, 2002, received December 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Denavir® (penciclovir cream) 1%.

We acknowledge receipt of your submissions dated:

December 10, 2002
August 7, 2003
September 10, 2003
October 3, 2003

This supplemental new drug application provides for the use of Denavir® (penciclovir cream) 1% for the treatment of recurrent herpes labialis (RHL) in children ages 12 and older.

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 (package insert submitted on October 3, 2003).

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 20-629/S-008." Approval of this submission by FDA is not required before the labeling is used.

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, this submission fulfills your Phase IV Post-Marketing Commitment to investigate the safety and effectiveness of Denavir® (penciclovir cream) 1% in pediatric patients.

Furthermore, 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 and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e. a "Dear Health Care Professional" letter), we request that 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

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, please call Donald W. Reese, PharmD, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

Enclosures: Final Printed labeling (product package insert)

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See next page

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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