DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-629

Novartis Consumer Health, Inc.
Attn: Cynthia Psaras, PhD.
Associate Director, Regulatory Affairs
200 Kimball Dr.
Parsippany, NJ 07054-0622

Dear Dr. Psaras:

Please refer to your supplemental new drug application dated 17 December 2002 received, 23 December 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Denavir® (penciclovir) cream 1%.

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 17 December 2002. Please note this approval letter and attached label supersedes the approval letter dated April 8, 2003.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Vasavi Reddy, RPh., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., MPH
Deputy Division Director
Division of Antiviral Drug Products

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

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/s/

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Jeffrey Murray
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