DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-302/S-005

Novartis Pharmaceuticals Corporation
Attention: James L. DeMartino, PhD
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Dr. DeMartino:

Please refer to your supplemental new drug application dated May 26, 2004, received May 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elidel (pimecrolimus) Cream, 1%.

We acknowledge receipt of your submission dated November 12, 2004.

This supplemental new drug application provides changes to the Carcinogenesis, Mutagenesis, Impairment of Fertility and Pregnancy sections of the package insert to include data obtained from reproductive and developmental toxicology studies.

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 (text for the package insert and text for the patient package insert) agreed upon on November 12, 2004.

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 purpose, this submission should be designated "FPL for approved Supplement NDA 21-302/S-005. Approval of this submission by FDA is not required before the labeling is used.

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 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 you 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, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan Wilkin, M.D.
Division Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Enclosure

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

/s/

Stanka Kukich
11/24/04 09:29:28 AM
sign off for Dr. Jonathan Wilkin, Division Director