DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-302/S-011

Novartis Pharmaceuticals Corporation
Attention: James DeMartino, Ph.D.
Director, Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. DeMartino:

Please refer to your supplemental new drug application dated August 31, 2005, received September 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elidel (pimcerolimus) Cream, 1%.

We reference our supplement request letter dated August 2, 2005.

We acknowledge receipt of your submissions dated October 3, 4, 25, and 27, November 10 and 14, December 8, 9, 10, 11, 12 (2), 13, 14, 16, 20, and 22, 2005; January 6 and 9, 2006.

This supplemental new drug application provides for labeling revisions to communicate risks associated with the use of Elidel Cream.

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 for the package insert, and text for medication guide).

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 21-302/S-011**." 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

When you issue the "Dear Health Care Professional" letter or any future letter communicating important information about this drug product, 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 Margo Owens, Regulatory Project Manager, at (301) 301-796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Acting Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

Stanka Kukich

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