DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-302/S-012

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

Dear Dr. DeMartino:

Please refer to your supplemental new drug application dated February 9, 2007, received February 13, 2007, 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 June 15, 2007.

This supplemental new drug application provides for revisions to the package insert. These revisions included a change in the protein binding information in the CLINICAL PHARMACOLOGY/ Pharmacokinetcs/*Distribution* section, the addition of the adverse event "skin discoloration" in the ADVERSE REACTIONS/Post-Marketing Events/*General* section, the deletion of statements regarding the absence of reports of accidental ingestion in the OVERDOSAGE section, and the correction of a typographical error in the DOSAGE AND ADMINISTRATION section of the labeling.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-302/S-012."

LETTERS TO HEALTH CARE PROFESSIONALS

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 an electronic copy of the letter to both this NDA and to the following address:

MEDWATCH
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Catherine Carr, Regulatory Project Manager, at (301) 796-2311.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
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/

Susan Walker
8/10/2007 09:18:08 AM