DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-302/S-004

Friedemann Scheck
REG CMC Manager
TRD/Global Regulatory CMC
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Scheck:

Please refer to your supplemental new drug application dated April 14, 2003 received April 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elidel (pimecrolimus) Cream 1%.

This "Changes Being Effected (CBE-0)" supplemental new drug application provides for the addition of the 60 g tube size of Elidel (pimecrolimus) Topical Cream 1%.

We have completed our review of this supplemental new drug application, and it is approved effective on the date of this letter.

This/these application(s) is/are 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, text for the patient package insert, immediate container and carton labels).

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Millie Wright, Regulatory Project Managers, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry III
Center for Drug Evaluation and Research

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

/s/

Wilson H. DeCamp
10/15/03 04:20:00 PM
approved