DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-452/S-016
NDA 19-452/S-019
NDA 19-452/S-020

Hill Dermaceuticals, Inc.
Attn: Jerry S. Roth, President
2650 South Mellonville Avenue
Sanford, Florida 32773-9311

Dear Mr. Roth:

Please refer to your supplemental new drug applications (sNDA) submitted under section 505(b)(1)/pursuant to section of the Federal Food, Drug, and Cosmetic Act for Derma-Smoothe/FS (fluocinolone acetonide) Topical Oil, 0.01% for the following sND:

sNDA	Letter Date	Receipt Date
016	September 17, 1999	September 20, 1999
019	March 31, 2003	April 2 2003
020	March 31, 2003	April 2, 2003

We acknowledge receipt of the following submissions:

sNDA 016	sNDA 019	sNDA 020
October 28, 2004	October 28, 2004	August 12, 2004
December 31, 2004	December 31, 2004	October 28, 2004
June 6, 2005	June 6, 2005	December 31, 2004
October 19, 2005	October 19, 2005	October 19, 2005
November 1, 2005	November 1, 2005	June 6, 2005
November 9, 2005	November 9, 2005	November 1, 2005
		November 9, 2005

Your submission of October 19, 2005 constituted a complete response to our June 9, 2003 action letter for sNDA 016 and our February 2, 2004 action letters for sNDA 019 and sNDA 020.

These supplemental new drug applications provide for the following:

- sNDA 016 provides for indication specific container, carton and package insert labeling for each indication: atopic dermatitis in adults and children 2 years and over and adult scalp psoriasis,

- sNDA 019 provides for local safety data for pediatric patients using Derma-Smoothe/FS on the face,

- sNDA 020 provides data concerning the safety of Derma-Smoothe/FS use by patients with peanut sensitivity.

We completed our review of these applications, as amended. These applications 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 enclosed labeling (text for the package insert, immediate container and carton labels).

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 supplements NDA 19-452/S-016, S-019 and S-020**." Approval of these submissions by FDA is not required before the labeling is used.

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

Please submit one market package of the drug product when it is available.

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) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Acting Division 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/

Jill Lindstrom

11/9/2005 06:04:57 PM