

Hill Dermaceuticals, Inc.
Innovative Dermatologicals for Children and Adults

March 1, 2007

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Mr. Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

Re: **Requirements that Must Be Met to Establish Bioequivalence
and Therapeutic Equivalence of Generic Versions
Fluocinolone Acetonide 0.01% Topical Oil to
Derma-Smoothe/FS® Scalp Oil and Derma-Smoothe/FS® Body Oil**

Dear Mr. Buehler:

This letter is in follow up to the Citizen's Petition of September 30, 2004 (2004P-0448), subsequent amendment to the Citizen's Petition of December 13, 2005, regarding the requirements that must be met to establish the bioequivalence and therapeutic equivalence of generic versions of Derma-Smoothe/FS® (fluocinolone acetonide 0.01%) Topical Oil (Scalp Oil) and Derma-Smoothe/FS® (fluocinolone acetonide 0.01%) Topical Oil (Body Oil), and several letters, for which we have yet to receive a substantive response. On March 26, 2005, the Agency issued an interim response to the Citizen Petition noting that the Agency was unable to reach a decision due to the need to address other Agency priorities and that the Agency will respond as soon as possible given the numerous demands on the Agency's resources. Again, I want to reiterate that as of today, the Agency has provided no substantive response to the Citizen Petition. This remains a cause of significant concern to us and I request that the Agency provide a detailed substantive response in the immediate future.

Upon rereading the September 30, 2004 Citizen's Petition, we noticed important items that we would like to bring to your attention:

1. In Section "A Action Requested" in the penultimate sentence of the first paragraph, the word "ointment" is a typographical error. It should read, "oil."

2004P-0448

AMD 2

2. Page 4 of the Petition, second paragraph, third sentence, states

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3. Please be advised that Hill is submitting experts' affidavits and references to the petition reiterating that the only way to establish bioequivalence and therapeutic equivalence of generic fluocinolone acetonide topical oil products is to conduct comparative clinical studies between the test and the reference products, Derma-Smoothe/FS® Scalp Oil and Derma-Smoothe/FS® Body Oil.

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5. Since our last correspondence, the Agency's Dermatology Branch completed its review of Hill's Supplemental Application to NDA 19-452, S-016, and approved the proposed, revised split labeling, i.e., separate labeling for Derma-Smoothe/FS® (Scalp Oil) and Derma-Smoothe/FS® (Body Oil) in its Nov 17, 2005 letter, a copy of which is enclosed for your reference. Since each product has unique labeling and distinct indications, separate and distinct comparative clinical studies are the only way to establish bioequivalence and therapeutic equivalence of generic fluocinolone acetonide topical oil products and the reference products, Derma-Smoothe/FS® (Scalp Oil) and Derma-Smoothe/FS® (Body Oil.)

Mr. Gary Buehler

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In addition, Hill has submitted a supplemental application to NDA 19-452 for Derma-Smothe/FS® Topical Oil for the indication atopic dermatitis for the pediatric population 3 months and older.

In conclusion, because these items are very important, I wanted to bring them to your direct attention. These items are being submitted to the Citizen Petition.

We respectfully request the expeditious review and substantive reply to the Citizen's Petition, subsequent amendments and letters referred to herein. The Petition has been pending for a very long time and it does present significant clinical and regulatory issues that must be addressed.

Very truly yours,

HILL DERMACEUTICALS, INC.


Jerry S. Roth
President

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Sanford, FL 32773-9361
(407) 323-1887
(407) 649-9213 fax

JSR: med

Cc: Jane Axelrad, Esq.

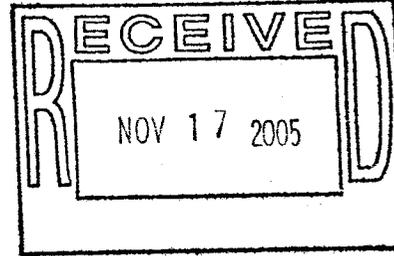


DEPARTMENT OF HEALTH & HUMAN SERVICES

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:

<u>sNDA</u>	<u>Letter Date</u>	<u>Receipt Date</u>
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:

<u>sNDA 016</u>	<u>sNDA 019</u>	<u>sNDA 020</u>
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