

Hill Dermaceuticals, Inc.
Innovative Dermatologicals for Children and Adults

3012 7 JUL 12 A8 57

July 11, 2007

VIA FACSIMILE AND FEDERAL EXPRESS

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. 2004P-0448
Response to Letter Dated June 26, 2007 From Jane Axelrad, Esq.**

Dear Sir/Madam:

This letter is in response to the letter dated June 26, 2007, from Jane Axelrad, Esq. regarding the above referenced Citizen Petition requesting documentation concerning the Agency's requirement of Hill Dermaceuticals, Inc. ("Hill") to conduct product specific stability data demonstrating the compatibility of the shower cap with the finished product.

Attached please find a redacted copy of the Agency's letter received by Hill on June 13, 2003, from Jonathan K. Wilkin, M.D., who was at that time, the Director of the Division of Dermatological and Dental Products, regarding NDA 19-452/S-016 concerning the Agency's requirement of Hill to demonstrate the compatibility of the shower cap with the finished product.

If you have any further questions, please do not hesitate to contact me.

Sincerely yours,


Jerry Roth
President
Hill Dermaceuticals, Inc.

Cc: Jane Axelrad, Esq.

2004P-0448

LET 5



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

RECEIVED

JUN 13 2003

NDA 19452/S-016

Hill Dermaceuticals, Inc.
Attention: Jerry S. Roth, President
2650 South McIlonville Avenue
Sanford, Florida 32773

Dear Mr. Roth:

Please refer to your supplemental new drug application dated _____, received _____, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Derma-Smoother/FS (fluocinolone acetonide) Topical Oil, 0.01%.

We acknowledge receipt of your submissions dated _____; and _____, and _____.

Your submission of _____ constituted a complete response to our _____ action letter.

This supplemental new drug application provided for an _____.

We have completed our review and find the information presented is inadequate, and the supplemental application is not approvable under section 505(d) of the Act and 21 CFR 314.125(b). The deficiencies may be summarized as follows:

1. _____
2. _____
3. _____
4. _____

5. Please provide:

a. I

b. Data or published information to support the compatibility of Derma Smoothe/FS product with the material of the shower cap.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

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

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research