

Hill Dermaceuticals, Inc.
Innovative Dermatologicals for Children and Adults

VIA FEDERAL EXPRESS

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

August 22, 2006

Docket No. 2004P-0448

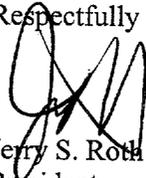
**Re: Requirements that Must Be Met to Establish Therapeutic Equivalence of Generic Versions
Fluocinolone Acetonide 0.01% topical oil to Derma-Smoothe/FS® Scalp Oil and Body Oil**

As you know, on September 30, 2004, Hill Dermaceuticals, Inc. ("Hill") submitted a Citizen Petition requesting the Commissioner of Food and Drugs not approve any generic equivalent version of the Petitioner's, Hill, proprietary drug product, *Derma-Smoothe/FS® Scalp Oil and Body Oil* (fluocinolone acetonide 0.01% topical oil) unless and until Abbreviated New Drug Application ("ANDA") applicants comply with statutory requirements to demonstrate that any proposed generic equivalent product has the same active ingredient, labeling, and conditions of use as the reference listed drug, *Derma-Smoothe/FS®*. In the petition Hill also requested that any ANDA applicant for fluocinolone acetonide topical oil must demonstrate bioequivalence which can only be done by conducting studies with clinical endpoints, the same as those established by Petitioner.

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. As of today, the Agency has provided no substantive response to the Citizen Petition.

On behalf of Hill, Howard I. Maibach, M.D. discusses the reasons ANDA applicants for fluocinolone acetonide topical oil must demonstrate bioequivalence and comply with statutory requirements to demonstrate that any proposed generic equivalent product has the same active ingredient, labeling, and conditions of use as the reference listed drug, *Derma-Smoothe/FS®*. The testimonial of Howard I. Maibach, M.D. is located in Appendix A of this submission.

Respectfully Submitted,



Jerry S. Roth
President
Hill Dermaceuticals, Inc.

Enclosures

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Appendix

- A. Dr. Howard I. Maibach Letter on Bioequivalence and Safety Issues Pertaining to Generic Versions of Derma-Smoothe/FS®
- B. Excerpt from the October 29 & 30, 2003 Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee of the Food and Drug Administration to review the safety data on Topical Immunomodulators and Topical Corticosteroids.
- C. Excerpt from the March 25, 2004 Joint Dermatologic and Ophthalmic Drug and Non-Prescription Drug Advisory Committee Meeting, Gaithersburg, Maryland.
- D. Data presented to the Advisory Committee, in PowerPoint presentation.
- E. Summary of Contact Urticaria (by Howard I. Maibach, MD)
- F. References: Bibliography of Howard I. Maibach, MD
- G. Amin S, Lahti A, Maibach H. Eds. Contact Urticaria Syndrome. CRC Press, New York, 1997.