

Hill Dermaceuticals, Inc. 7150 MAY 16 09:43
Innovative Dermatologicals for Children and Adults

VIA FEDERAL EXPRESS

Dockets Management Branch, HFA-305
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

May 15, 2007

RE: Amendment to Citizen Petition – 2004P-0448

Dear Sir / Madam:

Attached is the affidavit of Rosario G. Ramirez, MD. Hill Dermaceuticals, Inc. is requesting that this be docketed to the above referenced Citizen's Petition in support of the same.

Sincerely,



Jerry Roth
President

Enc.

2004P-0448

SUP 4

AFFIDAVIT OF ROSARIO G. RAMIREZ, M.D.
In Support of Citizen Petition, Docket 2004P-0448

State of Florida)
) ss.
County of Seminole)

BEFORE ME, the undersigned authority on this day personally appeared Rosario G. Ramirez, M. D., who, upon her oath duly deposed and stated as follows, to-wit:

1. This affidavit is made on my own personal knowledge and belief. I am over the age of 18 years, and otherwise *sui juris*. I testify as to the following matters based upon my own personal knowledge:

2. Educational Background – I earned my Medical degree from Far Eastern University, in Manila, Philippines. My undergraduate degree, Bachelor of Science in Zoology, was completed at the Universidad de Santo Tomas in Manila, Philippines.

3. My professional pharmaceutical industry experience is with Hill Dermaceuticals, Inc., as Director of Medical and Scientific Affairs as well as Regulatory Affairs.

4. As the responsible person for designing, carrying out and interpreting the results obtained from clinical studies, and understanding and complying with regulatory requirements and the new drug applications of dermatological products developed and manufactured by Hill Dermaceuticals, Inc., and my experience in the pharmaceutical industry, I am providing my comments on bioequivalence issues associated with Derma-Smoothe/FS[®] (fluocinolone acetonide) Topical Oil 0.01%, for possible generic versions of Derma-Smoothe/FS[®] Scalp Oil and Derma-Smoothe/FS[®] Body Oil.

5. It is my medical judgment that an applicant for a generic version of *Derma-Smoothie/FS*[®] must be required by FDA to conduct bioequivalence studies in peanut-allergic patients to assess the allergenic potential of the refined peanut oil ingredient used in the generic formulation,. It is my medical judgment that an applicant for a generic version of *Derma-Smoothie/FS*[®] must be required by FDA to conduct bioequivalence studies in atopic dermatitis patients, with disease involvement greater than 50% of body surface area, to assess the potential of the generic formulation to suppress HPA axis function. FDA must impose these requirements on ANDA applicants to ensure an objective comparison of the safety of the generic formulation with that of the innovator drug.

6. The clinical studies included in the labeling are specific studies conducted by Hill Dermaceuticals to demonstrate the safe and effective use of *Derma-Smoothie/FS*[®]. These studies were designed with precise and definite objectives to accommodate the unique peanut oil formulation of *Derma-Smoothie/FS*[®], and results of these safety studies cannot be extrapolated. Without a point-by-point comparison of innovator and generic products, on all the safety issues identified, addressed and resolved by Hill concerning *Derma-Smoothie/FS*[®], a generic version cannot use or reference those studies based on assumptions of similar response or effect. This is because the source of the peanut oil as well as the formulation in general, impacts safety parameters and product performance.

7. The clinical studies assessing the innovator drug potential for HPA axis suppression has established that *Derma-Smoothie/FS*[®] does not cause suppression of HPA axis in patients as young as 2 years of age. It is the only approved topical corticosteroid that showed no

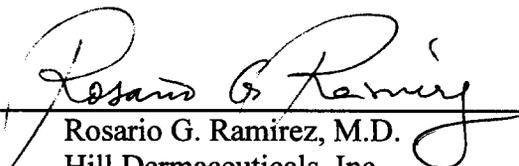
adrenal suppression, as demonstrated by these clinical studies where the drug was applied to as much as 90% of the body, for as long as 4 weeks twice daily use.

8. Unless an ANDA conducts bioequivalence studies in peanut-allergic patients and in atopic dermatitis patients to demonstrate bioequivalence, especially evaluating the safety parameters between *Derma-Smoothe/FS*[®] and the generic version, there is no scientific basis for an ANDA applicant to utilize labeling that references such studies. Due to Hill's unique, proprietary peanut oil based formulation, data included in the Insert Label for *Derma-Smoothe/FS*[®] on the safety studies, potential for HPA axis suppression and peanut allergenicity clinical studies, are not and will not be identical to any other product formulation including one that purports to be a generic equivalent of *Derma-Smoothe/FS*[®].

9. These issues are of major importance that should be addressed by the Agency.

I DECLARE under penalty of perjury that the foregoing is true and correct. Executed on this 15th day of May, 2007.

Further Affiant sayeth not.



Rosario G. Ramirez, M.D.
Hill Dermaceuticals, Inc.

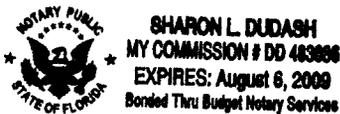
State of Florida)
) ss.
County of Seminole)

THE FOREGOING INSTRUMENT was acknowledged before me this 15th
day of May, 2007 by Rosario G. Ramirez, M.D..

[Please check below]

1. Personally known to me.
2. Who has produced _____ as identification.
 - a. Who did not take an oath.
 - b. Who did take an oath.

Given under my hand and official seal this 15th day of May, 2007.



[Notary Seal]

Sharon L. Dudash
NOTARY PUBLIC

Printed Name: Sharon L. Dudash

Notary Seal, State, and County aforesaid.

My Commission Expires: Aug 6 2009