

**Affidavit of Ralph Harkins, Ph.D.
In Support of Citizen Petition, Docket 2004P-0448**

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:

Educational Background and Professional Experience – I earned my doctorate degree in medical statistics and mathematical statistics with a minor in epidemiology from University of Oklahoma, OU Health Sciences Center, Oklahoma City, Oklahoma.

I have significant, relevant work experience in the field of biostatistics, including clinical trials design, development and management; statistical design and study analysis; management issues; electronic data capture implementation; and data quality. My professional pharmaceutical experience includes government service with the Food and Drug Administration as well as pharmaceutical industry experience both in-house and as an outside consultant in biostatistics and related areas.

I am the author of numerous articles on biostatistical methods and applications; a frequent speaker on biostatistical issues; and an active member of professional organizations, including the American Statistical Association, Drug Information Association, and Regulatory Affairs Professional Society.

Complete details concerning my educational and professional background are contained in the attached curriculum vitae (Attachment 1).

AFFIDAVIT

In light of my experience in biostatistics including experience in the evaluation of dermatological products, many containing topical corticosteroids, I am providing my comments on bioequivalence issues associated with topical oils containing a corticosteroid. More specifically, I am providing comments on the requirements to establish bioequivalence for possible generic versions of Derma-Smoothe/FS® Scalp Oil and Derma-Smoothe/FS® Body Oil.

1. Throughout my professional pharmaceutical career, I have been involved in the design and statistical analysis of safety and efficacy clinical studies. Many of these involved dermatological products, including studies used to establish the bioequivalence

of generic dermatological products to the FDA approved, reference listed brand name counterparts.

2. From my review and evaluation of the medical literature and my experience with designing and evaluating studies conducted using dermatological products, corticosteroid drug products administered to the scalp which are intended for local effects behave differently from corticosteroid drug products administered to other areas of the body which are intended for local effects.

3. From my review and evaluation of the medical literature plus my many discussions with medical experts in the field and experience with designing and evaluating studies conducted using dermatological products, and specifically topical corticosteroids, the vasoconstrictor assay is useful as a surrogate marker upon which to base bioequivalence determinations for certain, but not all, topical corticosteroid formulations, e.g., creams, ointments or gels..

4. From my review and evaluation of the medical literature plus my many discussions with medical experts in the field and experience with designing and evaluating studies conducted using dermatological products, and specifically topical corticosteroids, it is neither clinically appropriate nor relevant to use the vasoconstrictor assay as a surrogate marker upon which to base bioequivalence determinations for topical

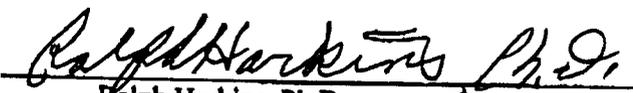
oil products, when used either on the scalp or on any other part of the body. Use of the vasoconstrictor assay as a surrogate marker to base bioequivalence determinations for topical oils will lead to erroneous conclusions.

5. In my professional opinion, the scientifically valid method to establish the bioequivalence of corticosteroids in topical oil formulations is for the ANDA or 505(b)(2) NDA applicant to conduct head-to-head equivalence studies comparing the test products to the approved reference listed drug products when used according to the conditions included in the approved labeling.

If the Agency has any questions or would like to further discuss my comments and recommendations, I am available to provide additional insight. Please feel to contact me at 732-748-3371 (phone); 908-319-2697 (cell).

I DECLARE under penalty of perjury that the foregoing is true and correct.

Executed on this 28 day of February, 2007.


Ralph Harkins, Ph.D.