DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-152

GlaxoSmithKline
Attn: Anthony Amitrano,
Director, US Regulatory Affairs
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Dear Mr. Amitrano:

Please refer to your new drug application (NDA) dated January 31, 2005, received February 1, 2005, submitted under section 505(b)(1) pursuant to of the Federal Food, Drug, and Cosmetic Act for CUTIVATE® (fluticasone propionate) Lotion, 0.05%.

We acknowledge receipt of your submissions dated March 17, 24, 25, 28, and 29, 30 (2), 2005.

The February 1, 2005, submission constituted a complete response to our January 12, 2005, action letter.

This new drug application provides for the use of CUTIVATE® (fluticasone propionate) Lotion, 0.05%, for the relief of the inflammatory and pruritic manifestations of atopic dermatitis in patients 1 year of age or older.

We completed our review of this application, as amended. It is 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 the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-152**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric local and systemic safety and systemic exposure studies for ages 3 months to 1 year until May 15, 2008.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered a required postmarketing study commitment. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric studies under PREA for the treatment of atopic dermatitis in pediatric patients ages 3 months to 1 year. These studies will evaluate the safety (both local and systemic, to include laboratory tests) and systemic exposure of this product.

Protocol Submission:	by November 15, 2005
Study Start:	by May 15, 2006
Final Report Submission:	by May 15, 2008

Submit final study report to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

We remind you of your postmarketing study commitment in your submission dated March 29, 2005.

1. Conduct a study to determine the photoco-carcinogenic potential of CUTIVATE® (fluticasone propionate) Lotion, 0.05%.

Dose Range Finding Study:	by October 1, 2005
Protocol Submission:	by August 1, 2006
Study Start:	by February 1, 2007
Final Report Submission:	by August 1, 2009

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatologic and Dental Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}
Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonathan Wilkin

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