NDA 19-958/S-008

GlaxoWellcome
Attention: Janice P. McKellar
Associate Director, Regulatory Affairs
Five Moore Drive
PO Box 13398
Research Triangle Park, North Carolina 27709-3398

Dear Ms. McKellar:

Please refer to your supplemental new drug application dated December 16, 1998, received December 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cutivate (fluticasone propionate cream) Cream, 0.05%.

We acknowledge receipt of your submissions dated February 11, June 2, 3, and 4, 1999. Your submission of December 16, 1998, constituted a complete response to our June 6, 1996, action letter.

This supplemental new drug application provides for the use of Cutivate (fluticasone propionate cream) Cream, 0.05%, for use in pediatric patients 3 months of age or older with corticosteroid-responsive dermatoses.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed final version of the labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed final version of the labeling text. Marketing of the product with FPL that is not identical to this enclosed, revised, final labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-958/S-008." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

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