DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-337/S-005

GlaxoSmithKline Consumer Health
Attention: Joseph Zuccarini
Associate Director, US Regulatory Affairs
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Dear Mr. Zuccarini:

Please refer to your supplemental new drug application dated August 10, 2000, received August 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TEMOVATE® (clobetasol propionate gel) Gel, 0.05%.

We acknowledge receipt of your submissions dated January 28, 2002 and July 3, 2002.

This special supplemental new drug application changes being effected provides for the addition of Geriatric Use subsections to the PRECAUTIONS and the DOSAGE AND ADMINISTRATION sections in the labeling.

We completed our review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on August 10, 2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter. However we have the following request.

Please revise the labeling for NDA 20-337 to be compliant with the requirements under 21 CFR 201.57(f)(10) at the next printing as follows:

- In the PRECAUTIONS section, Geriatric Use subsection revise the label to read:

  Clinical studies of TEMOVATE® (clobetasol propionate gel) Gel, 0.05% in US clinical trials did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious.

- Delete the Geriatric Use subsection in the DOSAGE AND ADMINISTRATION section.

Report the above requested revisions in the Annual Report to NDA 20-337.

If a letter communicating important information about this drug products (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

If additional information relating to the safety or effectiveness of these drugs becomes available, revision of the labeling may be necessary.

If you have any questions, call Melinda Harris, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

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

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

/s/

John Kelsey
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for Dr. Wilkin