NDA 20-511 S-002

GlaxoSmithKline Consumer Healthcare
Attention: Anthony G. Amitrano
Director, US Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Amitrano:

We acknowledge your supplemental new drug application, dated May 26, 1999, received June 01, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aphthasol (amlexanox) Oral Paste, 5%.

This supplemental application provides information that there were not enough geriatric patients in the clinical studies to determine whether they differed from younger patients in their response to Aphthasol. In addition to the changes regarding geriatric use, there are changes in the "Information for Patients" section.

We have completed the review of this supplemental application, including the submitted draft labeling, 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 agreed upon enclosed approved labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed approved labeling text.

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 10 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "Final Printed Labeling" for approved supplemental NDA 20-511/S-002. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the label may be required.

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

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

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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, please contact Kalyani Bhatt, Project Manager, at (301) 827-2020.

Sincerely yours,

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/

Markham Luke
6/11/02 05:09:15 PM
Acting for Dr. Jonathan Wilkin, Director, Division of Dermatologic and Dental Drug Products