DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-828/S-009
NDA 20-209/S-005

GlaxoSmithKline Consumer HealthCare, L.P.
Attention: Larry S. Alphas
Manager, U.S. Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Mr. Alphas:

Please refer to your August 10, 2000, supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OXISTAT (oxiconazole nitrate) Cream, 1%, and Lotion, 1%.

We acknowledge receipt of your submissions dated July 22 and 29, 2003, and January 22 and 23, 2004 (facsimiles).

Your submissions of July 22, 2003, constituted a complete response to our December 16, 2002, action letter.

These supplemental new drug applications provide for addition of the Geriatric Use sub-section to the PRECAUTIONS Section of the labeling.

We have completed our review of these applications, as amended. These applications are 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).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 19-828/S-009 and NDA 20-209/S-005." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, please call Frank H. Cross, Jr, M.A., CDR, Senior Regulatory Management Officer, 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

Enclosure

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

/s/

Stanka Kukich
1/23/04 02:54:28 PM
signing for Dr. Jonathan Wilkin, Division Director