DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAY 19 1998

John B. West, Jr.
Assistant Director
Dermatology Regulatory Affairs
GlaxoWellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

RE: NDA 19-828
Oxistat® (oxiconazole nitrate cream) Cream, 1%
MACMIS ID# 6333

Dear: Mr. West:

Reference is made to GlaxoWellcome Inc.'s (Glaxo) June 9, 1997, and January 6, 1998, submissions of promotional materials under cover of FDA Form-2253 for Oxistat® (oxiconazole nitrate cream) Cream, 1%. As part of the Division of Drug Marketing, Advertising, and Communications' (DDMAC) routine monitoring of prescription drug advertising, DDMAC has reviewed the sales aids identified as OXI323RO and OXI340RO, and has determined that they are in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically,

- The materials are misleading because Glaxo makes comparative claims based on *in vitro* activity data by presenting *in vitro* activity of different antifungal agents, when there are no data from no head-to-head clinical trials to substantiate the implied claims. For example, the tables comparing the *in vitro* activity of Oxistat to commonly available topical antifungal agents suggest Oxistat is superior based on its *in vitro* activity.

  In addition, Oxistat is not indicated to treat infections caused by all the listed fungal microorganisms. Therefore, the presentation suggests that Oxistat is useful in a broader range of conditions than indicated.

- The claim, "Once-a-day dosing is easier on the patient and may enhance

patient compliance" is misleading without substantiation.

- The chart showing the percent of patients achieving "High mycologic cure rates 2 weeks post therapy" would be misleading because it selectively provides only the "mycologic cure" rates to imply greater effectiveness than demonstrated in the clinical trials. For example, the labeling lists "treatment success" (Both a global eradication ≥90% clinical improvement and a microbiologic eradication at the 2-week post-treatment visit) rates of 43% for Oxistat versus 14% for vehicle at 2 weeks. In addition, the presentation fails to define mycologic cure as "No evidence (culture and KOH preparation) of the baseline (original) pathogen in a specimen from the affected area taken at the 2-week post-treatment visit (for tinea versicolor, mycologic cure was limited to KOH only).

DDMAC requests that Glaxo take the following actions:

1. Immediately discontinue the use of the above identified sales aids and all other advertising and promotional labeling pieces having the same or similar violations.

2. Submit to the undersigned a written response of Glaxo's intent to comply with number one, on or before June 3, 1998.

If Glaxo has any questions or comments, please contact me by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to the MACMIS ID 6333, in addition to the NDA number.

Sincerely,

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications