DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

DEC 16 1998

Joy E. Ferrell
Director, Dermatology Regulatory Affairs
Glaxo Wellcome, Inc.
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

RE: NDA# 19-958
Cutivate (fluticasone propionate) cream, 0.05%
MACMIS ID # 7384

Dear Ms. Ferrell:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of Glaxo Wellcome, Inc.'s (Glaxo) promotional materials for Cutivate (fluticasone propionate) cream that are false, misleading, and in violation of the Federal Food, Drug, and Cosmetic Act. The materials include, but are not limited to, a journal advertisement identified as CUT293RO that appeared in *Infectious Diseases in Children.* Specifically, DDMAC objects to the following:

The header "eczema management for a lifetime" is misleading because it implies that Cutivate may be used for patients of all ages. However, Cutivate is not approved for use in pediatric patients. In fact, the approved product labeling for Cutivate states that the safety and effectiveness in pediatric patients have not been established and provides precautionary information about the risk of HPA axis suppression and reports of striae in infants and children.

Advertisements are false or otherwise misleading if they contain a representation or suggestion, not approved or permitted for use in the labeling, that a drug is more effective than has been demonstrated by substantial evidence. DDMAC has previously notified Glaxo of similar violations in other promotional materials for Cutivate in November of 1996.

DDMAC is concerned about the repeated violation concerning the misleading promotion of a broader indication and will continue to closely monitor Glaxo's compliance with the regulations. DDMAC may determine that other remedial measures will be necessary to fully correct such false and/or misleading messages.

To address the objections in this letter, DDMAC recommends that Glaxo immediately discontinue the use of this violative journal advertisement and all other promotional materials for Cutivate that explicitly or implicitly make the same or similar claims. Please respond to this letter, in writing, by January 4, 1999. This response should include a list of all violative promotional materials and Glaxo's methods for discontinuing their use.

If Glaxo has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this particular matter, please refer to MACMIS ID #7384 in addition to the NDA number.

Sincerely,

Leah Palmer, Pharm.D.
Branch Chief
Division of Drug Marketing,
Advertising and Communications