DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 10 1997

TRANSMITTED VIA FACSIMILE

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

RE: NDA #19-958
Cutivate (fluticasone propionate) cream, 0.05%
MACMIS ID #4498

Dear Ms. Ferrell:

This letter is in reference to promotional materials submitted under cover of FDA Form 2253 by Glaxo Wellcome Inc. (Glaxo) to the Division of Drug Marketing, Advertising and Communications (DDMAC) on February 13, and March 12, 1997. These promotional materials are identified as CUT219RO and CUT238RO. These promotional materials are misleading and therefore in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations.

Specifically, these materials are misleading because they suggest that Cutivate is better or safer than has been demonstrated by substantial evidence. These materials make this suggestion by using the phrase "soft molecule Cutivate," and similar statements. The phrase is used in a manner that suggests that Cutivate is either safer because it is a soft molecule, or that Cutivate is preferred for delivery because it is a soft molecule.

However, the phrase "soft molecule" is not generally known, and these promotional materials do not adequately define the phrase to place the claims in proper context. Such proper context would clearly indicate that to the extent Cutivate meets Glaxo's definition of a "soft molecule," its status as a soft molecule confers no clinical benefit.

Glaxo should immediately stop disseminating these and any similarly violative materials. In addition, DDMAC requests that Glaxo provide DDMAC with a written statement of your intention to stop disseminating such material on or before April 17, 1997. Your response should be directed to the undersigned.

If Glaxo has any questions or comments, please contact the undersigned in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely,

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