DEPARTMEN HEALTH & HUMAN SERVICES

Pu alth Service

Food and Drug Administration
Rockville MD 20857

SEP 11 1997

TRANSMITTED VIA FACSIMILE

Michele M. Hardy
Director, Advertising and Labeling Policy
Glaxo Wellcome, Inc.
5 Moore Drive
Research Triangle Park, NC 27709

RE: **NDA#** 20-121
Flonase (fluticasone propionate) nasal spray, 0.05%w/w
MACMIS ID # 5705

Dear Ms. Hardy:

This letter concerns a broadcast product ad in the form of a 1-800-FLONASE recorded telephone advertisement in use by Glaxo Wellcome, Inc. (Glaxo) for Flonase Nasal Spray. DDMAC considers this broadcast product ad to be violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations because it does not provide adequate provision of the approved product labeling.

The 1-800-Flonase telephone script recording represents a full product ad in the form of a broadcast ad. Under the regulations, a broadcast ad must include a "major statement" and adequate provision of the approved product labeling or presentation of a brief summary of all necessary information related to side effects and contraindications. However, the Flonase product materials are not received in a timely manner (as was the circumstance recently when the 1-800 telephone number was called). DDMAC does not consider a two-three week actual response time for receipt of the approved product labeling to meet the "adequate provision" requirement.

DDMAC requests that further distribution and use of this telephone broadcast ad, as well as any other similarly violative recorded telephone scripts for other Glaxo products, cease immediately.

Glaxo should respond to DDMAC in writing no later than September 25, 1997, with a description of its plan to address this issue.

If you have any questions, please contact the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Glaxo that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 5705 in addition to the NDA number.

Sincerely,

Warren Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications