DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

AUG 18 1999

George J. Morrow
President & CEO
Glaxo Wellcome, Inc.
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Re: NDA 20-121
Flonase (fluticasone propionate) Nasal Spray
MACMIS ID # 8025

WARNING LETTER

Dear Mr. Morrow:

This Warning Letter addresses Glaxo Wellcome, Inc.'s ("Glaxo's") dissemination of a television broadcast advertisement for Flonase (fluticasone propionate) Nasal Spray ("Flonase"). The advertisement was broadcast in Spanish in the Commonwealth of Puerto Rico in 1998 and 1999. The Division of Drug Marketing, Advertising, and Communications ("DDMAC") has reviewed this advertisement as part of its monitoring and surveillance program. DDMAC has concluded that Glaxo's television advertisement is lacking in fair balance or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the "Act") and applicable regulations. See 21 U. S. C. §§ 321(n), 331(a)&(b), 352(n).

Under 21 U.S.C. § 352(n), all prescription drug advertisements must contain a true statement of information in brief summary relating to side effects, contraindications, and effectiveness, as required by FDA regulations. The prescription drug regulations at 21 C.F.R. § 202.1(e)(1) provide that television broadcast advertisements shall include (1) information relating to the major side effects and contraindications of the advertised drug in the audio or audio and visual presentation, and, (2) unless "adequate provision" is made for the dissemination of the approved labeling in connection with the broadcast, a brief summary of all necessary information related to side effects and

contraindications. DDMAC concludes from its review of Glaxo's advertisement that Glaxo failed: to provide information relating to the major side effects and contraindications; and, to make adequate provision for the dissemination of the approved labeling or inclusion of the brief summary of information related to side effects and contraindications in conjunction with the advertisement. In fact, the advertisement mentions only the indication for Flonase (relief of nasal allergy symptoms) and provides no risk information at all.

Finally, although this television advertisement was broadcast in both 1998 and 1999, Glaxo failed to submit the advertisement to FDA. Such submissions are required at the time of the advertisement's first use under the postmarketing reporting requirements. (21 C.F.R. § 314.81(b)(3)(i))

Conclusions and Requested Actions

It is our understanding that this advertisement has been discontinued in Puerto Rico. However, DDMAC has concluded that Glaxo's activities resulted in the dissemination of misleading and incomplete information about Flonase. Accordingly, Glaxo should assure FDA that similar advertisements are not being disseminated anywhere in the United States or its territories and possessions. In addition, Glaxo should propose an action plan to disseminate accurate and complete information to the audience that received the misleading message. Glaxo's action plan should be submitted to DDMAC for approval. After such approval, the action plan should be implemented as soon as possible.

The violations discussed in this letter do not necessarily constitute an exhaustive list. We are continuing to evaluate other aspects of Glaxo's promotional campaign for Flonase and we may determine that additional remedial measures will be necessary to fully correct the false or misleading messages resulting from Glaxo's violative conduct.

Glaxo should respond to this letter no later than September 7, 1999. If Glaxo has any questions or comments, please contact Thomas W. Abrams, R.Ph., M.B.A., Leah M. Palmer, Pharm. D., or Lesley R. Frank, Ph.D., J.D., 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. DDMAC reminds Glaxo that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 8025.

Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

Sincerely,

/S/

Norman A. Drezin, R.Ph., J.D.
Acting Director
Division of Drug Marketing,
Advertising, and Communications