DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFDN

Food and Drug Administration
Rockville MD 20857

OCT 10 1997

TRANSMITTED VIA FACSIMILE

Ms. Barbara A. Thompson
Assistant Director, Advertising Policy
Regulatory Affairs
Glaxo Wellcome Inc.
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

RE: NDA# 20-121
Flonase (fluticasone propionate) Nasal Spray
MACMIS ID# 5820

Dear Ms. Thompson:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Flonase (fluticasone propionate) Nasal Spray, (e.g., brochure FLN642RO entitled "Designed for Speed") which DDMAC has determined contain claims that are misleading, contain unsubstantiated implied superiority claims, and lack fair balance and therefore violate the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

The overall presentation of the brochure's back page is misleading. The page intermingles clinical efficacy claims and pharmacology claims in a way that suggests clinical superiority of Flonase over other nasal steroids based on nonclinical data and accompanying in vitro comparative data table, and accompanying in vivo comparative data table) when in fact no such clinical significance has been demonstrated. Furthermore, even if the claims were not intermingled, the footnoted disclaimers to the pharmacology claims are not presented with a prominence and readability that are reasonably comparable to its nonclinical claims to effectively disclaim clinical relevance.

In addition, the two comparative pharmacology tables alternately use data of different beclomethasone formulations to selectively promote or "cherry pick" data more favorable to Flonase (table entitled uses beclomethasone monopropionate, and table entitled ' uses beclomethasone dipropionate). These presentations are particularly misleading given that beclomethasone monopropionate is not a U.S. approved formulation, and that this qualification

was not disclosed in the comparative table. Moreover, the "Data on File" information GW provided to support the referenced pharmacology claims are inadequate to substantiate or explain the derivation of the above comparative tables.

Finally, the brochure lacks fair balance in disclosing the most common side effects to its strong clinical claims

In light of these efficacy claims, disclosures restricted to information about onset of action and expected degree of relief do not provide sufficient balancing risk information.

GW should cease use of this material and similarly violative materials immediately. GW should provide a written response, including a list of all violative materials and its plan of action. GW's written response should be received by October 20, 1997, and should be directed to 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 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds GW that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5820 in addition to the NDA number.

Sincerely,

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications