DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

FEB 28 1997

TRANSMITTED VIA FACSIMILE

Michele M. Hardy
Director, Advertising & Labeling Policy
Regulatory Affairs
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 # 5201

Dear Ms. Hardy:

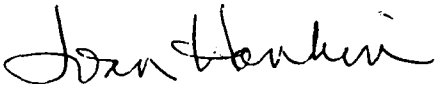
As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials (e.g., FLN530RO, FLN525RO) disseminated by Glaxo Wellcome Inc. (GW) for Flonase (fluticasone propionate) Nasal Spray that contain promotional claims that lack fair balance and are misleading. Therefore, DDMAC considers these materials to be violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

These direct-to-consumer letters, headlined in bold "Ask your doctor about Flonase, because it is possible to get *same-day relief* for your nasal allergy symptoms" (italics in original), contain multiple onset of action claims that lack fair balance because the qualifying language is not sufficiently prominent nor proximate to the variously highlighted "fast/same-day relief" claims.

Therefore, GW should immedately cease its use of these or similar promotional materials. GW's written response should be received by DDMAC no later than March 14, 1997. GW's response should be sent 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 17B-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 # 5201 in addition to the NDA number.

Sincerely,



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

File Name: flonase\dtconset.nov

Drafted:	HANKIN	Date: 2/27/97
Concur with Comment:	ABRAMS	Date: 2/2/897
Revised:	HANKIN	Date: 2/28/97

CC:
HFD-40/NDA # 20-121
HFD-40/Chron/HANKIN(2)/ABRAMS

MACMIS ID # 5201

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 49042 Material ID#: FLN525RO

2253 ID#: 49250 Material ID#: FLN530RO

Due Date: March 14, 1997

Close Out: N

FOI STATUS: RELEASABLE