DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDI

Food and Drug Administration
Rockville MD 20857

APR 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# 20-548**
Flovent (fluticasone propionate) Inhalation Aerosol
44 mcg, 110 mcg, and 220 mcg
MACMIS ID# 5248

Dear Ms. Hardy:

This letter concerns promotional material (i.e., detail aid FLO176RO) for Flovent (fluticasone propionate) Inhalation Aerosol 44 mcg, 110 mcg, and 220 mcg disseminated by Glaxo Wellcome Inc. (GW) that contains the comparative claim "(For patients with persistent asthma) Efficacy comparable to BDP [beclomethasone dipropionate] at half the dose" and that is referenced as being substantiated, in part, by the 1994 Leblanc[1] study. This claim is also referenced to the Dahl[2] study in the promotional piece.

The Division of Drug Marketing, Advertising, and Communications (DDMAC), in consultation with the Division of Pulmonary Drug Products (DPDP), has determined that the Flovent comparable efficacy at half the BDP dose claim has not been demonstrated by substantial evidence (i.e., adequate and well-controlled studies). The Leblanc study does not provide a basis for drawing any firm conclusions on the relative efficacy of BDP and Flovent because of design and methodological issues, including the lack of multiple dose levels and lack of placebo arm.

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1 Leblanc P, Mink S, Keistinen T, et al., "A comparison of fluticasone propionate 200 ug/day with beclomethasone dipropionate 400 ug/day in adult asthma". Allergy. 1994; 49:380-385.

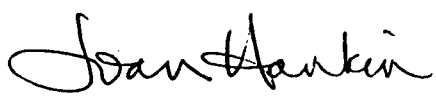
2 Dahl R, Lundback B, Malo J-L, et al. "A dose-ranging study of fluticasone propionate in adult patients with moderate asthma". Chest. November 1993;104:1352-1358.

Consequently, one cannot conclude that any of the efficacy parameter improvements seen for both products represent true drug effect, nor does one know the ability of the trial's design and conduct to identify a difference between these agents in efficacy, if one were to exist. Thus, although overall the reported efficacy of these products at the studied doses appears to be similar, no definitive conclusion can be drawn from Leblanc on the comparability of BDP to Flovent.

Therefore, DDMAC has concluded that GW disseminated promotional material for Flovent that contain this comparative statement is false and/or misleading in violation of the Federal Food, Drug, and Cosmetic Act and regulations. GW should immediately cease its dissemination and use of promotional materials that contain this or similar claims. GW's written response should include a description of its plan to address this issue. GW's written response should be recieved by DDMAC no later than May 12, 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 #5248 in addition to the NDA number.

Sincerely,



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

File Name: flovent\leblanc.nov

Consult:	MEYER:	Date: 4/15/97
Drafted:	HANKIN	Date: 4/16/97
Concur:	ABRAMS	Date: 4/22/97

CC:
HFD-40/NDA #20-548
HFD-40/Chron/HANKIN(2)/ABRAMS
HFD-570/NDA #20-548
HFD-570/MEYER

MACMIS ID # 5248

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 49488 Material ID#: FLO176R0, February 1997

Due Date: May 12, 1997

Close Out: N

FOI STATUS: RELEASABLE