DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG - 4 1998

TRANSMITTED VIA FACSIMILE

Ms. Michele M. Hardy
Director, Advertising Policy
Regulatory Affairs
Glaxo Wellcome Inc.
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Re: NDA# 20-548
Flovent (fluticasone propionate) Inhalation Aerosol
44 mcg, 110 mg, 220 mcg
MACMIS ID#: 6878

Dear Ms. Hardy:

This letter concerns promotional activities and materials disseminated by Glaxo Wellcome Inc. (GW) for Flovent (fluticasone propionate) Inhalation Aerosol (MDI) that was previously discussed in 1998 correspondence with the Division of Drug Marketing, Advertising, and Communications (DDMAC).

DDMAC has received another specimen of Flovent 44 mcg sample boxes overstickered "NOW 4YRS. AND UP" being distributed in San Jose, California. On March 13, 1998, DDMAC had previously expressed concern about the potential safety risks arising from use of this product in an unapproved pediatric patient population (Flovent MDI is indicated for patients 12 years of age and older). DDMAC has concluded that GW is disseminating Flovent product packaging that contains a false or misleading promotional claim in violation of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

On March 26, 1998, GW responded to DDMAC's March 13, 1998, inquiry letter about similar reports of Flovent MDI promotion in an unapproved population. GW responded, in pertinent part, that it was interested in eliminating any potential confusion regarding use of Flovent Inhalation Aerosol in the pediatric population. As a result of DDMAC's March 13, 1998, letter, GW stated it sent a voicemail communication (March 16, 1998) and a written communication (March 17, 1998) to the sales force responsible for detailing the respiratory products to reiterate the appropriate use of the stickers (copies submitted to DDMAC).

Such promotion of Flovent MDI is inconsistent with the approved product labeling in promotion an unapproved use, and misbrands the product. Therefore, GW should immediately cease its use of Flovent packaging and promotional materials that contains this oversticker. GW's written response should be received by DDMAC no later than August 18, 1998, describing the steps that GW has taken to ensure that use of these materials has been suspended and any such written or verbal representations have been corrected to avoid potential safety risks arising from use of this product in children ages 4-11.

Please direct your response 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, Maryland 20857. DDMAC reminds GW that only written communications are considered official.

In future correspondence regarding this particular matter, please refer to MACMIS ID# 6878 in addition to the NDA number.

Sincerely,

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