



Food and Drug Administration  
Rockville MD 20857

NOV 30 1999

**TRANSMITTED VIA FACSIMILE**

C. Elaine Jones, Ph.D.  
Product Director, 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 mcg, 220 mcg  
MACMIS ID#: 8428

Dear Dr. Jones:

This letter concerns a direct-to-consumer (DTC) promotional labeling piece (i.e., a fulfillment letter/FL0525RO) sent by Glaxo Wellcome, Inc. (GW) after consumers called a 1-800 telephone number for product information about Flovent (fluticasone propionate) Inhalation Aerosol.

The letter states "Prevent inflammation—control asthma symptoms better" and includes the headline, "Flovent...the medication that helps you control your asthma symptoms better." The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this piece of promotion labeling and concluded that it is misleading because this claim lacks context (i.e., better asthma control than with use of short-acting beta-agonists alone) and suggests or implies Flovent is more efficacious to other asthma treatments than has been demonstrated by substantial evidence.

GW should immediately cease its dissemination and use of all promotional materials for Flovent with this misleading claim. We should receive your written response no later than December 14, 1999, and it should list all similarly violative materials, with a description of your method of discontinuation. Your response 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-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857. We remind GW that only written communications are considered official.

C. Elaine Jones, Ph.D.  
Glaxo Wellcome Inc.  
NDA# 20-548

Page 2

In future correspondence regarding this particular matter, please refer to MACMIS ID# 8428 in addition to the NDA number.

Sincerely,

**/S/**

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