



OCT 30 1997

**TRANSMITTED VIA FACSIMILE**

Ms. Barbara A. Thompson  
Assistant 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# 5556

Dear Ms. Thompson:

This letter concerns a direct-to-consumer print ad (ACP133RO) for Flovent (fluticasone propionate) Inhalation Aerosol disseminated by Glaxo Wellcome Inc. (GW). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has determined that the presentation of this ad contains an unsubstantiated implied efficacy claim for an unapproved use that is misleading, as well as lacks fair balance. Therefore, this ad violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations. GW should immediately cease its dissemination and use of promotional materials that contain this or similar claims.

The totality of elements that compose GW's ad featuring celebrity athletic spokesperson Jackie Joyner Kersee suggest an unapproved indication for Flovent (i.e., prevention of exercise induced bronchospasm or "EIB") that is inconsistent with the approved product labeling. These elements misleadingly suggest that Flovent is effective in a broader range of asthma patients (i.e., those suffering from asthma bronchospasm brought on by exercise) than has been demonstrated by substantial evidence.

The elements that create this misleading suggestion of effectiveness for EIB include:

- the banner headline "Winning with Asthma: Jackie Joyner Kersee (captioned) World Champion and Three-Time Gold Medal Winner"
- the prominent photographic image of Ms. Kersee engaged in strenuous physical activity (i.e., running and inhaling deeply);

- the testimonial statements of Ms. Kersee ("It's simple...Flovent helps make breathing easier"; "I thought I was really in control of my asthma. But then my doctor gave me Flovent. What a change! I can breathe easier now. Breathe deeply. I feel great! Don't wait another second. Talk to your doctor today about Flovent.")

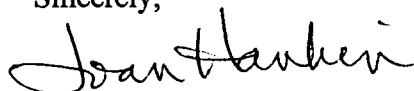
Taken together the visual image of Ms. Kersee, the "Winning with Asthma" headline banner and caption of athletic titles, and the testimonial statements suggest that Flovent is indicated and effective for prevention of EIB. Furthermore, the ad's balancing statements ("Flovent is NOT indicated for the relief of sudden asthma symptoms", "Prevents swelling of the airways that causes asthma symptoms" and "Individual results may vary") do not adequately convey the contextual risk information because they are not presented with a prominence reasonably comparable to the much more impactful and compelling photographic image involving strenuous physical activity.

Moreover, given the running/athletic imagery and accompanying athletic titles (world champion and three-time Olympic gold medal winner), the disclosure of the product's indication and contraindication statements do not adequately clarify that Flovent is not indicated for prevention of exercise-induced bronchospasm and that other asthma medications, such as fast-acting beta-agonists would still be appropriate not only for relief of acute symptoms, but also for prevention of EIB. Finally, the ad also lacks fair balance for the following reasons. The general boxed warning (applicable to all strengths of Flovent) regarding the risk of adrenal suppression when transferring from oral corticosteroids has been omitted. Also, the listing of common drug-related side effects in clinical trials minimizes the incidence of these events in patients taking Flovent Inhalation Aerosol at various doses and is inconsistent with the approved product labeling.

GW's written response should include a description of its plan to address this issue. GW's written response should be received by DDMAC no later than November 14, 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 #5556 in addition to the NDA number.

Sincerely,



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