



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 17 1999

Michele Hardy  
Director, Advertising and Labeling Policy  
Regulatory Affairs  
GlaxoWellcome, Inc.  
Five Moore Drive  
P.O. Box 13398  
Research Triangle Park, NC 27709

Re: **NDA 20-121**  
**Flonase (fluticasone propionate) Nasal Spray**  
**MACMIS ID #8294**

Dear Ms. Hardy:

This letter addresses GlaxoWellcome, Inc.'s (Glaxo) dissemination of a television broadcast "reminder" advertisement for Flonase (fluticasone propionate) Nasal Spray. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program and has concluded that the advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the drug product. Flonase is indicated for the management of nasal symptoms of seasonal and perennial allergic and nonallergic rhinitis. By presenting a person in an environment that contains allergens, such as flowers, grasses, and trees, and then showing the person taking a deep breath, the Flonase advertisement makes a representation about the drug product

DDMAC requests that Glaxo immediately cease using this advertisement and all other promotional materials for Flonase that contain the same or similar claims or presentations. Glaxo should submit a written response to DDMAC, on or before October 1, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Glaxo should include a list of all promotional materials that were discontinued, and the discontinuation date.

Ms. Michele Hardy  
GlaxoWellcome, Inc.  
NDA 20-121

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Glaxo should direct its response to Joan Hankin, JD, by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS #8294 and NDA 20-121.

Sincerely,

**/S/**

Leah Palmer, Pharm.D.  
Branch Chief  
Division of Drug Marketing,  
Advertising, and Communications