



MAR 14 2000

**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# 20-121**  
Flonase (fluticasone propionate) Nasal Spray  
MACMIS ID# 8781

Dear Dr. Jones:

This letter addresses Glaxo Wellcome Inc.'s (GW) dissemination of a newspaper "reminder" advertisement for Flonase (fluticasone propionate) Nasal Spray (FL2049RO/AAAAI supplement for USA Today). The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed this advertisement as part of its monitoring and surveillance program and concludes 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. By stating "More and more doctors agree..." ("All you want is Flonase Nasal Spray.") and asking "Why suffer through another day?", the Flonase advertisement makes a representation about the drug product.

GW should immediately cease using this advertisement and all other promotional materials for Flonase that contain the same or similar claims or presentations. We should receive your written response no later than March 28, 2000, and it should list all similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

Your response should be directed to the undersigned by facsimile at (301) 594-6771, or to the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind GW that only written communications are considered official.

C. Elaine Jones, Ph.D.  
Glaxo Wellcome Inc.  
NDA# 20-121

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In all future correspondence regarding this particular matter, please refer to MACMIS ID # 8781 in addition to the NDA number.

Sincerely,

**/S/**

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



More and more doctors agree...

"All you want is FLONASE Nasal Spray."

Why suffer through another day?

Ask your doctor about FLONASE Nasal Spray...

or call 1-800-FLONASE.

When your doctor writes your prescription,  
you'll be glad you took the time.

All you want is FLONASE.

**FLONASE<sup>®</sup>**  
(fluticasone propionate)

NASAL SPRAY, 50 mcg



GlaxoWellcome

For information and a \$5.00 rebate coupon, call 1-800-FLONASE (1-800-356-6273) or visit [www.flonase.com](http://www.flonase.com)

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THIS ADVERTISEMENT PREPARED BY  
JOB NO: Glaxo-Wellcome  
CLIENT: Flonase  
PRODUCT: FLA 01 070

SPACE/SIZE: 8 1/2" x 9 1/2" 4/C  
PUBS: AAAAI Sup. for USA Today  
ISSUE: March 3, 2000