

Food and Drug Administration Rockville MD 20857

MAR 1 4 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.

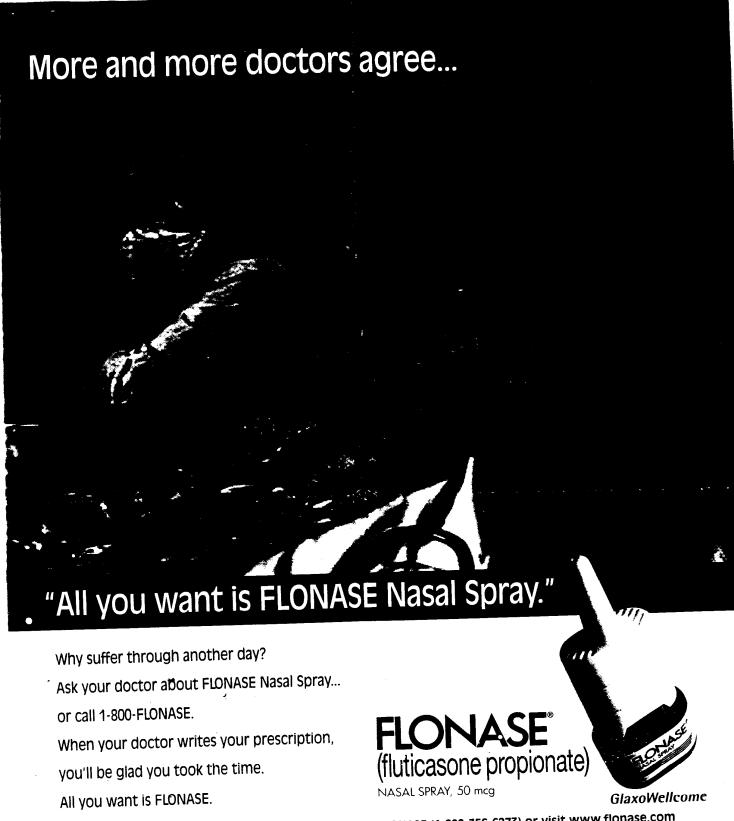
In all future correspondence regarding this particular matter, please refer to MACMIS ID # 8781 in addition to the NDA number.

Sincerely,

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

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For information and a \$5.00 rebate coupon, call 1-800-FLONASE (1-800-356-6273) or visit www.flonase.com ©2000 Glaxo Wellcome Inc. All rights reserved. Printed in USA. FL2049R0 January 2000

THIS ADVERTISEMENT PREPARED BY JOB NO:Glaxo-Wellcome

CLIENT: Flonase

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