



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 10 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# 8784

Dear Dr. Jones:

This letter addresses Glaxo Wellcome Inc.'s (GW) dissemination of a television (TV) broadcast advertisements for Flonase (fluticasone propionate) Nasal Spray (45 second/FLN2055RO and 60 second/FLN2056RO). The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed these TV advertisements as part of its monitoring and surveillance program and concludes that they violate the Federal Food, Drug, and Cosmetic Act and applicable regulations.

The TV advertisements claim Flonase relieves the specific nasal allergy symptom of post-nasal drip (PND). However, GW has not provided substantial evidence demonstrating that Flonase is effective in treating this particular nasal allergy symptom. Therefore, because these PND efficacy claims are unsubstantiated, they are false or misleading.

GW should immediately cease using these TV advertisements 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 24, 2000. It should list 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 at 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# 8784 in addition to the NDA number.

Sincerely,

/S/

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

VIDEO

"Multi-symptom Allergies/Doc Rev."

AUDIO

Title: "Multi-symptom Allergies/Doc REV" Page 1 of 2
Date: 2/22/00
Length: TV :60

SUPER: nasal allergies

SUPER: DOCTOR
DRAMATIZATION



DOCTOR: I see lot's of people with allergies. But the ones with multi-symptom nasal allergies, they're suffering with it all...that annoying postnasal drip, the sneezing, itchy, runny nose, the nasal congestion...

SUPER: multi-symptom
FLONASE



For those kinds of allergies...I prescribe multi-symptom Flonase.

SUPER: NASAL SPRAY,
50 MCG



ANNCR (VO): Flonase Nasal Spray

SUPER: AVAILABLE
BY PRESCRIPTION
ONLY



once a day relieves all nasal allergy symptoms, even post nasal drip.

SUPER:
GLAXO WELLCOME



WOMAN: All it takes is Flonase.

SUPER: Results may vary

Product: FLONASE
Art Director:

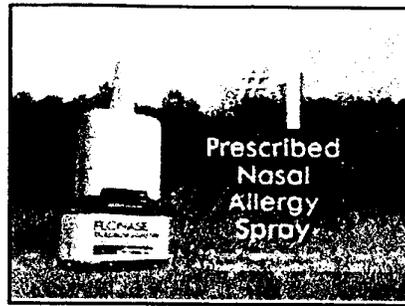
Client: Glaxo Wellcome
Writer:

Title: Multi-symptom Allergies/Doc Rev
Page 2 of 2
Date: 2/22/00
Length: TV :60

Product: FLONASE
Art Director:

Client: Glaxo Wellcome
Writer:

SUPER: SOURCE:
PRESCRIPTION
AUDIT (SPA). TOTAL U. S.
PRESCRIPTIONS,
DECEMBER 1999.
SCOTT-LEVIN



ANNCR (VO): The number one prescribed nasal allergy spray.

SUPER: Maximum relief may take several days



Even kids as young as 4 can use Flonase. For best results, use daily.

SUPER: CALL TO LEARN MORE OR ASK YOUR DOCTOR



If side effects occur, they are generally mild and may include headache, nosebleed or sore throat.

SUPER: 1-877-FLONASE
www.flonase.com
\$5 Savings



And now, all it takes is a toll-free phone call to get a \$5 savings certificate for Flonase plus valuable allergy information and the latest Allergy Talk newsletter. Call to learn more. Ask your doctor about multi-symptom Flonase.

FRAME NOT PICTURED
SUPER: See our ad in LIFE magazine

SUPER: Postnasal drip, Congestion, Runny Nose, Sneezing, Itchy Nose



DOCTOR: When you get it all, all it takes is Flonase.

Final frame (Not Pictured): Flonase logo

VIDEO

"Multi-symptom Allergies/Doc Rev."

AUDIO

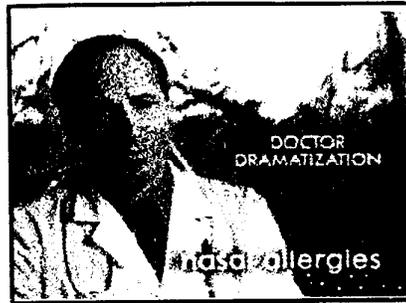
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Length: TV:45

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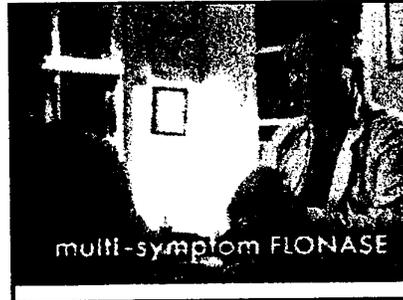
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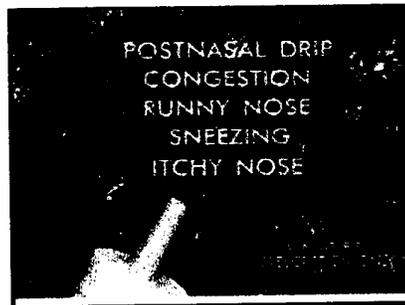
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