



NOV 23 1999

TRANSMITTED VIA FACSIMILE

Michele M. Hardy
Director, Advertising and Labeling Policy
Regulatory Affairs
Glaxo Wellcome Inc.
Five Moore Drive
P.O. Box 13398
Research Triangle Park
North Carolina 27709

**RE: NDA 21-036
Relenza (zanamivir for inhalation)
MACMIS ID#8509**

Dear Ms. Hardy:

This letter concerns Glaxo Wellcome Inc.'s (GW) promotional materials for Relenza. As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the TV broadcast advertisement for Relenza, "Home Again," submitted by GW under cover of Form FDA 2253 on November 11, 1999. From its review, DDMAC has concluded that GW has distributed materials that are false and/or misleading, in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Misleading Efficacy Presentation

The overall presentation in the advertisement is misleading because it suggests that Relenza is more effective than has been demonstrated by substantial evidence. Specifically, the images misleadingly suggest that Relenza has been shown to eliminate the flu more quickly and completely than has been demonstrated. According to the product labeling, results suggested up to one day of shortening of median time to improvement, not elimination, in major symptoms of influenza in patients receiving Relenza compared to those receiving placebo. The definition of time to improvement was no fever and self-assessment of "none" or "mild," meaning flu symptoms may still persist—to suggest otherwise is misleading. In fact, some fluctuation of symptoms was observed even after patients reached the defined time to improvement. Further, the statements, "...to help you start feeling better sooner" and "It may take a few days to see results," are neither sufficiently prominent nor adequate to overcome the impact of the misleading efficacy presentation.

GW should immediately discontinue the use of this broadcast advertisement and other promotional materials or activities that contain these or similar claims. GW should respond in writing no later than December 8, 1999, describing its plan to comply. GW should also include a list of materials being discontinued, as well as the date of discontinuation.

Your response should be directed to Ele Ibarra-Pratt by fax at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, 17B-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 #8509 in addition to the NDA number.

Sincerely,

A handwritten signature in black ink, appearing to be 'EIP' or similar initials, written over a horizontal line.

Ele Ibarra-Pratt, R.N., M.P.H.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications



TITLE: "HOME AGAIN DR" :60
AGENCY: []
CLIENT: GLAXO WELLCOME
[]

SFX: DING DONG



WOMAN: WHO IS IT?



FLU: IT'S ME INFLUENZA, YOU KNOW, THE
FLU (BREATHS ON PEEP-HOLE).



FLU: COMIN' IN.



ANNCR: HE'S INFLUENZA
FLU: HOW ARE YA!



ANNCR: AND HE'LL MAKE YOU MISERABLE
WITH SYMPTOMS LIKE FATIGUE...



ANNCR: ...HIGH FEVER, COUGH,
HEADACHE AND BODY ACHES.



FLU: PEOPLE SAY I HAVE AN INFECTIOUS
LAUGH.



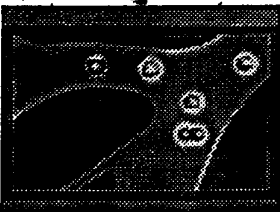
FLU: WHADDYA YOU THINK?!



FLU: (LAUGHS)



ANNCR: INTRODUCING RELENZA, A NEW
PRESCRIPTION MEDICINE TO HELP YOU
START FEELING BETTER SOONER.
(SUPER)
RELENZA ZANAMIVIR FOR INHALATION
(SUPER)
START WITHIN 2 DAYS OF
SYMPTOM ONSET.



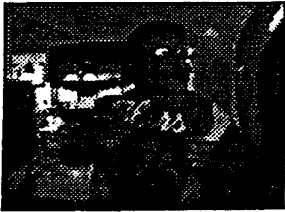
ANNCR: THE VIRUS THAT CAUSES THE FLU
LIVES IN THE LUNGS.



WOMAN: GO AWAY.



ANNCR: IF YOU THINK YOU HAVE SYMPTOMS OF THE FLU...
SFX: KNOCK ON DOOR.



ANNCR: ...TALK TO YOUR DOCTOR RIGHT AWAY.
SFX: BAGPIPES.



FLU: I'M NOT BUGGING YOU, AM I?
WOMAN: (MOANS)



ANNCR: RELENZA IS AN ANTI-VIRAL MEDICINE THAT'S INHALED. YOU SHOULD BE SHOWN HOW TO USE THE INHALER.
(SUPER)
YOU SHOULD BE SHOWN HOW TO USE THE INHALER.



ANNCR: THOSE WITH CHRONIC LUNG DISEASE OR ASTHMA MAY EXPERIENCE WHEEZING AND SHOULD CONSULT THEIR DOCTOR.

(SUPER)
WWW.RELENZA.COM



ANNCR: SIDE EFFECTS OCCURRED IN 3% OR LESS OF PATIENTS AND INCLUDED NAUSEA, DIARRHEA AND SINUSITIS.
(SUPER)
FOR PRODUCT INFORMATION ASK YOUR DOCTOR OR PHARMACIST



FLU: I'M NOT READY TO TRAVEL....
(SUPER)
IT MAY TAKE A FEW DAYS TO SEE RESULTS



FLU: ...I HAVEN'T WASHED OUT MY THINGS...
(SUPER)
IT MAY TAKE A FEW DAYS TO SEE RESULTS



FLU: ...I'M GONNA MISS YOUR BIRTHDAY.
(SUPER)
IT MAY TAKE A FEW DAYS TO SEE RESULTS



ANNCR: IF YOUR DOCTOR SAYS IT'S INFLUENZA, ASK ABOUT RELENZA.
(SUPER)
RELENZA ZANAMIVIR FOR INHALATION
(SUPER)
1-877-HELP FLU
(SUPER)
GLAXO WELLCOME LOGO



SFX: DOOR SLAM
FLU: WELL, I NEVER.
(SUPER)
SEE OUR AD IN LIFE MAGAZINE