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TRANSMITTED VIA FACSIMILE

Michele M. Hardy
Director, Advertising and Labeling Policy
Regulatory Affairs
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park NC 27709

RE: Valtrex (valacyclovir HCl) Caplets
NDA #20-550
MACMIS #7552

Dear Ms. Hardy:

This letter addresses Glaxo Wellcome Inc.'s (Glaxo's) dissemination of a journal advertisement for Valtrex (valacyclovir HCl) Caplets (VAL481R1). This advertisement was published in Time magazine in October 1998 and in Total Well-Being in summer 1998. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program. DDMAC has concluded that Glaxo's advertisement is false or misleading and lacking in fair balance in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 331(a)(b) & 352(n), and applicable regulations.

Promotional materials must present information about the risks associated with the use of the drug in a manner reasonably comparable to that of claims concerning the drug's efficacy. This advertisement fails to present sufficient information relating to the most common adverse events, warnings, or precautions associated with Valtrex. For example, the advertisement fails to include the most common adverse events (other than headache which is mentioned) such as nausea, abdominal pain, etc.

Additionally, the advertisement presents, in small type, isolated from the main body of the advertisement, important information found in the precautions section of the approved product labeling (i.e., that there is no cure for genital herpes, that Valtrex may not suppress all outbreaks of genital herpes, and the fact that it may be possible to spread genital herpes while taking Valtrex). In contrast, the major promotional emphasis is on the "header," "IT'S ABOUT SUPPRESSION," and its accompanying

statement that "VALTREX once-a-day is proven to suppress genital herpes outbreaks ahead of time in many people." The presentation of precaution information is not sufficient to provide prominence and readability comparable with the presentation of information relating to the effectiveness of Valtrex.

In order to address the objections cited in this letter, DDMAC suggests that Glaxo take the following actions:

(1) Immediately discontinue the dissemination of this advertisement and all other promotional materials for Valtrex bearing the same or similar violative presentations upon receipt of this letter.

(2) Provide to DDMAC, in writing, Glaxo's commitment to comply with number one above.

Glaxo's response should be received no later than February 12, 1999. If Glaxo has any questions or comments, please contact the undersigned or Sherrie Shade R.Ph., J.D., by facsimile at 301-594-6771, or in writing at the Division of Drug, Marketing, advertising, and Communications, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Glaxo that only written communications are considered official.

In all correspondence related to this matter, please refer to MACMIS #7552, in addition to the NDA numbers.

Sincerely,

Lesley R. Frank, Ph.D., J.D.
Regulatory Counsel,
Division of Drug Marketing, Advertising,
and Communications