

FOI

Food and Drug Administration  
Rockville MD 20857

JAN 28

**TRANSMITTED VIA FACSIMILE**

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

**RE: NDA 20-550**  
Valtrex (valacyclovir HCl) Caplets  
MACMIS ID #5034

Dear Ms. Hardy:

Reference is made to Glaxo Wellcome's (Glaxo) December 10, 1996, FDA Form 2253 submission of a reminder TV advertisement (VAL299RO) for Valtrex. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this item and finds it in violation of the Federal Food, Drug, and Cosmetic Act (Act) and the applicable regulations. Reference is also made to Glaxo's January 8, and 13, 1997, submissions of proposed revised TV advertisements.

- As discussed in our January 7, 1997, teleconference, the original TV ad is misleading because it is not considered to be a reminder advertisement for Valtrex because it makes representations or suggestions about the advertised product. For example, the mention of the drug Zovirax and the statement "Now there's something else..." makes a representation about the availability of another safe and effective product, i.e., Valtrex.
- The revised TV advertisement submitted on January 8, 1997, would also not be considered a reminder advertisement because it makes a representation about Valtrex. Specifically, the ad continues to imply that another therapy is now available for use in treating the uses for which Zovirax is indicated for.
- The revised TV advertisement submitted on January 13, 1997, although revised to a disease oriented advertisement for genital herpes, would be misleading because it prompts

consumers to call a phone number for a "free trial." Since this would be a free trial of a pharmaceutical product, the ad would still be considered a drug ad. During our teleconference on January 13, 1997, DDMAC requested that the phrase "free-trial" be deleted from the ad.

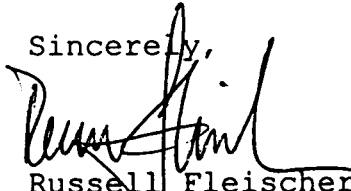
In order to address these objections, DDMAC recommends that Glaxo take the following actions:

1. Discontinue the use of the original TV advertisement by January 31, 1997.
2. Revise the TV advertisement to be consistent with the requests made during our January 13, 1997, teleconference.
3. Provide to DDMAC, in writing, Glaxo's intent to comply with number one and two above.

Glaxo's response should be received by February 12, 1997. If Glaxo has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #5034, in addition to the NDA number.

Sincerely,



Russell Fleischer, PA-C, MPH  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications

Ms. Michele Hardy  
Glaxo Wellcome Inc.  
NDA 20-550

Page 3

File Name: val5034.nov

Drafted:	Fleischer	Date:	1/15/97
Comment:	Palmer	Date:	1/16/97
Comment:	O'Brien	Date:	1/22/97
Revised:	Fleischer	Date:	1/23/97
Concur:	Drezin	Date:	1/27/97

CC:  
HFD-40/NDA 20-550  
HFD-40/Chron/Fleischer/Palmer  
HFD-530/NDA 20-550  
HFD-530/Cvetkovich

MACMIS File ID#: 5034

MACMIS Type Code: LETT  
MACMIS Action Code: VIOL  
2253 ID#: 47192  
2253 Material Code: CTV  
Material ID#: VAL299RO  
Due Date: February 12, 1997  
Close Out: N

FOI STATUS: RELEASABLE