DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDI

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

File Name: val5034.nov

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|---|---|---|
| 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