



FOI

Food and Drug Administration  
Rockville MD 20857

MAR 11 1997

**TRANSMITTED VIA FACSIMILE**

Edward Yuhas, Ph.D.  
Associate Director  
U.S. Regulatory Affairs  
SmithKline Beecham Pharmaceuticals  
One Franklin Plaza  
Philadelphia, Pennsylvania 19101

**RE: NDA 20-363**  
Famvir (famciclovir)  
MACMIS ID #5225

Dear Dr. Yuhas:

Reference is made to the SmithKline Beecham's (SB) February 6, 1997, Form FDA 2253 submission of a direct-to-consumer advertisement (FV7916) for Famvir. The Division of Drug Marketing, Advertising and Communications (DDMAC), has reviewed this advertisement and finds it in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Specifically, the advertisement fails to present Famvir's side effects and other important safety information with a prominence and readability comparable to the information presented on efficacy.

In order to address this objection, DDMAC recommends that SB take the following actions:

1. Immediately discontinue the publication of the above referenced advertisement.
2. Provide to DDMAC, in writing, SB's intent to comply with number one above.

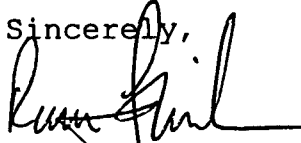
SB's response should be received by March 25, 1997. If SB has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

Dr. Edward Yuhas  
SmithKline Beecham Pharmaceuticals  
NDA 20-363

Page 2

In all correspondence related to this matter, please refer to  
MACMIS ID #5225, in addition to the NDA number.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell Fleischer". The signature is written in a cursive style with a long horizontal stroke at the end.

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

Dr. Edward Yuhas  
SmithKline Beecham Pharmaceuticals  
NDA 20-363

Page 3

File Name: fam5225.nov

Drafted: Fleischer Date: 3/10/97  
Comment: Date:  
Revised: Date:  
Concur: Palmer Date: 3/10/97

CC:  
HFD-40/NDA 20-363  
HFD-40/Chron/Fleischer/Palmer  
HFD-530/NDA 20-363  
HFD-530/Kukich/Cvetkovich

MACMIS File ID#: 5225

MACMIS Type Code: LETT  
MACMIS Action Code: VIOL  
2253 ID#: 49498  
2253 Material Code: CAD  
Material ID#: FV7916  
Due Date: March 25, 1997  
Close Out: N

FOI STATUS: RELEASABLE