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RESEARCH**

**APPLICATION NUMBER: 20-550/S-012**

**PHARMACOLOGY REVIEW**

PHARMACOLOGIST'S REVIEW

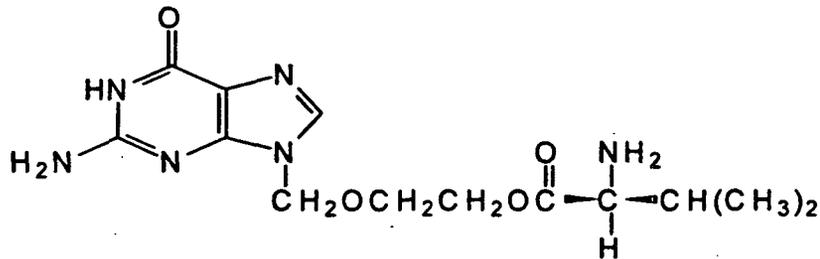
NDA 20-550 (S-012)

Date Submitted: August 30, 2000  
Date Assigned: September 3, 2000  
Date Completed: February 7, 2001  
HFD-530

SPONSOR: Glaxo Wellcome Inc.  
Five Moore Dr.  
Research Triangle Park, NC 27709

DRUG: Valacyclovir hydrochloride; Valtrex.

STRUCTURE:



FORMULATION: 500 mg and 1 gm caplets.

RELATED INDS: IND 34,526  
NDA 20-487

INDICATION(S): Treatment of recurrent Genital Herpes Simplex  
Virus Infections.

INTRODUCTION: This submission is a supplemental application to  
provide for a labeling indication for a shorter treatment course  
of three days for Valtrex Caplets in the treatment of recurrent

episodes of genital herpes.

**LABELING CHANGES:** The suggested changes to the preclinical pharmacology/toxicology sections of the label are as follows:

- 1) \_\_\_\_\_
- 2) \_\_\_\_\_
- 3) line 247, correct Pregnancy Registry numbers if necessary.

C. Anita H. Bigger, Ph.D.  
Pharmacologist

**Concurrences:**

HFD-530/JFarrelly  
HFD-530/ABigger 2-7-01

**Disk:**

HFD-530/JFarrelly

**cc:**

HFD-530 Original IND  
HFD-530 Division File  
HFD-340  
HFD-530/Supervisory Medical Officer  
HFD-530/Medical Officer  
HFD-530/Microbiology  
HFD-530/Chemistry  
HFD-530/ABigger  
HFD-530/KYoung

/s/

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Anita Bigger  
2/12/01 11:50:35 AM  
PHARMACOLOGIST

James Farrelly  
2/13/01 12:27:00 PM  
PHARMACOLOGIST