

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-478

PHARMACOLOGY REVIEW

PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21-478 (000)

Sequence number/date/type of submission: 000/March 29, 2002/original

Information to sponsor: Yes () No (x)

Sponsor and/or agent: GlaxoSmithKline Inc.

Five Moore Drive

Research Triangle Park, NC 27709

Reviewer name: C. Anita H. Bigger, PhD

Division name: Division of Antiviral Drug Products

HFD #: 530

Review completion date: December 11, 2002

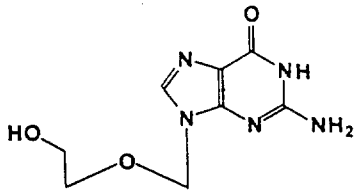
Drug:

Trade name: Zovirax Cream 5%

Generic name: Acyclovir

Chemical name: _____

Structure:



Relevant INDs/NDAs/DMFs: IND : _____ NDA 18-828; NDA 18-604.

Drug class: Acyclovir is a synthetic purine nucleoside analogue with *in vitro* and *in vivo* inhibitory activity against human herpes viruses.

Indication: Treatment of recurrent herpes labialis (cold sores).

Clinical formulation: 5% cream.

Route of administration: Topical

COMMENTS

Acyclovir is an approved drug (NDA 18-904) for treatment of herpes labialis (cold sores). The present NDA is for acyclovir in a cream formulation. No new pharmacology/toxicology data were submitted with this NDA. There were no proposed labeling changes in the pharmacology/toxicology sections of the label. There are no pharmacology/toxicology issues with this NDA.

Reviewer signature: _____

Supervisor signature: Concurrence - _____

cc: list:

HFD-530 Original IND
HFD-530 Division File
HFD-340
HFD-530 TWu
HFD-530 BNilambar
HFD-530/ZGu
HFD-530/ABigger
HFD-530 Biopharm
HFD-530.FSmith
HFD-530 SBelouin

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/s/

Anita Bigger
12/13/02 10:02:49 AM
PHARMACOLOGIST

James Farrelly
12/13/02 03:36:12 PM
PHARMACOLOGIST