CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-550/S-012

CLINICAL PHARMACOLOGY BIOPHARMACEUTICS REVIEW

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW: ADDENDUM

NDA: 20-550 (SE-2) **REVIEWER:** Jooran S. Kim, Pharm.D.
TYPE: Supplemental Application: **SUBMITTED:** 8/30/00
Treatment of Recurrent Genital Herpes **DRAFT REVIEW:** 4/24/01
DRUG: valacyclovir hydrocloride (VALTREX)
FORMULATION: Oral caplets
SPONSOR: Glaxo Wellcome

BACKGROUND: Valtrex was initially approved on June 23, 1995 for the treatment of herpes zoster in immunocompromised adults and was subsequently approved for the treatment of recurrent genital herpes in immunocompetent adults on December 15, 1995 (NDA 20-550). The sponsor is seeking approval for a shorter treatment course for the latter indication from 500 mg po bid for five days to 500 mg po bid for three days.

No action was indicated (NAI) from a Clinical Pharmacology and Biopharmaceutics perspective because this supplemental NDA was supported by clinical data (Study HS2A4004) only. Upon further review of the label, we have one addendum to the proposed label.

PROPOSED LABELING CHANGE:

1.0 CLINICAL PHARMACOLOGY

1.1 Pharmacokinetics

Metabolism:

~~[redacted]~~

To: "Neither valacyclovir nor acyclovir are metabolized by cytochrome P450 enzymes."

RECOMMENDATIONS:

This label is acceptable from a Clinical Pharmacology and Biopharmaceutics perspective.

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Concurrence:

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/s/

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BIOPHARMACEUTICS

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5/3/01 04:32:04 PM
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