



NDA 20-487 /S-016

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Sherman Alfors
Director, Antiviral/Antibacterial
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated and received March 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex® 500 mg and 1 g caplets.

This Prior Approval Supplemental new drug application provides for the following revision:

- To update the Warnings and Precautions section of the package insert to include information pertaining to CNS adverse events in adult and pediatric patients.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the content labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling(SPL) format submitted on March 12, 2010.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-487/S-016.**"

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact Venessa M Perry, MPH, Regulatory Project Manager, at 301.796.4891.

Sincerely,

{See appended electronic signature page}

/Kendall Marcus, MD/

for Debra Birnkrant, M.D.

Director

Division of Antiviral Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research

Enclosures:

Package Insert

Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20487	SUPPL-16	GLAXOSMITHKLIN E	VALTREX (VALACYCLOVIR HCL) CAPLETS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VENESSA M PERRY
04/19/2010

KENDALL A MARCUS
04/19/2010