September 3, 2008

This approval letter is a correction of the letter mailed to the sponsor on September 2, 2008 which had a typographical error on page one. This corrected letter, which was finalized on September 3, 2008, references the September 2, 2008 approval letter and shows the correction and it also states that the application is "approved effective the date this letter." The PM emailed a copy to the sponsor with a signature page that showed a September 3, 2008 date but that version was never officially mailed.

In accordance with policy, this corrected approval letter has been backdated to September 2, 2008 to maintain the original date of the action. This backdated letter will be officially mailed to the sponsor. The attributes of the original incorrect letter have been changed to Advice and an explanatory note added.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-487/S-014

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

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated December 10, 2007, received December 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VALTREX® (valacyclovir hydrochloride) Caplets.

We acknowledge receipt of your submissions dated:

February 15, 2008	February 19, 2008	February 29, 2008	March 3, 2008	March 13, 2008
March 18, 2008	March 27, 2008	April 8, 2008	May 2, 2008	May 8, 2008
May 19, 2009	May 28, 2009	June 4, 2008	June 10, 2008	June 19, 2008
July 16, 2008	July 23, 2008	July 29, 2008	August 5, 2008	August 25, 2008

Also refer to the September 2, 2008 approval letter, which listed pediatric patients > 2 years to 18 years of age as the appropriate patient population. The following correction is being made at this time:

This supplemental new drug application provides for the use of VALTREX® (valacyclovir hydrochloride) Caplets for the treatment of chickenpox in children 2 to < 18 years of age.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert submitted August 25, 2008**,** patient package insert submitted August 25, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-487/S014."

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 25, 2008, patient package insert submitted August 25, 2008).

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirements for chickenpox in children < 2 years of age for this application because necessary studies are impossible or highly impractical because the number of patients with this disease is very small.

We note that you have fulfilled the pediatric study requirement for ages 2 to < 18 years of age for this application.

Submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package insert(s) directly to:

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

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

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, call Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (Final Draft Label)

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

/s/

Debra Birnkrant
9/2/2008 03:10:31 PM
NDA 20-487