DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022509 **NDA APPROVAL**

GlaxoSmithKline
Attention: Elizabeth McConnell, PharmD
Associate Director, Neurology, US Regulatory Affairs
PO Box 13398; Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. McConnell:

Please refer to your new drug application (NDA) dated and received March 31, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamictal XR (lamotrigine) Extended-Release Tablets.

We acknowledge receipt of your submissions dated:

June 19, 2009	July 27, 2009	July 28, 2009
November 6, 2009	December 11, 2009	December 17, 2009
December 21, 2009	January 18, 2010	

This new drug application provides for the use of Lamictal XR (lamotrigine) as adjunctive therapy for Primary Generalized Tonic-Clonic (PGTC) seizures in patients ≥ 13 years of age.

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

CONTENT OF LABELING

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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, and Medication Guide). For administrative purposes, please designate this submission, "**SPL for approved NDA 022509**."

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels identical to those submitted on March 31, 2009 and, as revised on July 28, 2009, as soon as they are available, but no more than 30 days after

they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022509**". Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

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 requirement for ages birth up to 2 years because the necessary studies are impossible or highly impracticable. This is because there are too few children in this age group with the disease to study.

This product is appropriately labeled for use in ages 2 years to 12 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 13 years to 16 years for this application.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

We acknowledge receipt of your submission dated January 18, 2010, which includes a proposed modification to your Risk Evaluation and Mitigation Strategy (REMS) that was approved on May 29, 2009 with the original approval of NDA 022115, and an assessment of your approved REMS consisting of a statement that the Medication Guide would be adequate with the proposed modifications to achieve its purpose. Your proposed REMS modification contains a revised Medication Guide to include the new indication, and the removal of the other Lamictal formulations from the REMS document. As discussed on January 15, 2010, because Lamictal XR (lamotrigine) and the other Lamictal formulations do not share the same Medication Guide, they may not be included in the same REMS.

Your proposed modified REMS, submitted on January 18, 2010, and appended to this letter, is approved. The REMS consists of a Medication Guide and the timetable for submission of assessments of the REMS that was approved for Lamictal XR (lamotrigine) on May 29, 2009.

The REMS assessment plan for Lamictal XR (lamotrigine) should include but is not limited to an evaluation of patients' understanding of the serious risks of Lamictal XR (lamotrigine).

The REMS for the other formulations of Lamictal (NDAs 020241, 020764, and 022251) which was approved on May 8, 2009, remains unchanged.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022115 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022115
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022115
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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 safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 022115 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the SPL and final printed labeling requested above.

If you have any questions, call Dorothy Demczar, Pharm.D., Regulatory Project Manager, at (301) 796-2263.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Division Director
Division of Neurology Products
Office of Drug Evaluation I
Center of Drug Evaluation and Research

Enclosures:
Content of Labeling
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22509	ORIG-1	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	LAMICTAL XR(LAMOTRIGINE)ORAL TABLETS

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

/s/

RUSSELL G KATZ
01/29/2010