DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022115/S-001/S-005 **SUPPLEMENT 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 the following Supplemental New Drug Applications (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lamictal XR (lamotrigine) extended release tablets, 300mg.

Application	Submitted on:	Received on:	This "Prior Approval" supplement proposes:
NDA 22115/S-001	July 31, 2009	July 31, 2009	An additional dosage strength (300mg) for Lamictal XR.
NDA 22115/S-005	January 18, 2010	January 18, 2010	Proposed modification to the approved risk evaluation and mitigation strategy (REMS)

We acknowledge receipt of your additional submissions dated December 15, 2009 (S-001) and March 23, 2010 (S-005). We acknowledge receipt of your REMS assessment dated January 18, 2010.

Your submission of December 15, 2009 constituted a complete response to our November 30, 2009 action letter for S-001.

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

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 agreed-upon labeling text. 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 022115/S-001/S-005."**

Please also amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling in SPL that includes the changes approved in this supplemental application.

We request that the revised 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 that are identical to the submitted carton and immediate container labels, on July 31, 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 22115/S-001 and S-005**." Approval of this submission by FDA is not required before the labeling is used.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Lamictal XR (lamotrigine) was originally approved on May 29, 2009 and a REMS modification was approved on January 29, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. The proposed modified REMS consists of a Medication Guide revised to includes the addition of the approved 300 mg formulation.

Your proposed modified REMS, submitted on March 23, 2010 and appended to this letter, is approved. The REMS consists of a Medication Guide and a timetable for submission of assessments.

The timetable for submission of assessments of the REMS will remain the same as that approved on May 29, 2009 and January 29, 2010.

There are no changes to the REMS assessment plan described in our May 29, 2009, letter.

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(s) 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(s), 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 decide to issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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, call Dorothy Demczar, Pharm.D., Regulatory Project Manager, at (301) 796-2263.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure(s)
Content of Labeling
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22115	SUPPL-5	SMITHKLINE BEECHAM CORP	LAMICTAL XR TABLETS
NDA-22115	SUPPL-1	SMITHKLINE BEECHAM CORP	LAMICTAL XR 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
04/14/2010