DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020241/S-035 & S-040
NDA 020764/S-028 & S-033
NDA 022251/S-009 & S-002
NDA 022115/S-014 & S-004

SUPPLEMENT APPROVAL

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

Dear Dr. McConnell:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

Application	Product Name	Submitted on:	Received on:
NDA 020241/S-035	Lamictal (lamotrigine) tablets	December 17, 2008	December 17, 2008
NDA 020764/S-028	Lamictal (lamotrigine) chewable dispersible tablets	December 17, 2008	December 17, 2008
NDA 022251/S-009	Lamictal ODT (lamotrigine) orally disintegrating tablets	February 1, 2011	February 1, 2011
NDA 022115/S-014	Lamictal XR (lamotrigine) extended-release tablets	February 14, 2014	February 14, 2014
NDA 020241/S-040	Lamictal (lamotrigine) tablets	November 13, 2009	November 13, 2009
NDA 020764/S-033	Lamictal (lamotrigine) chewable dispersible tablets	November 13, 2009	November 13, 2009
NDA 022251/S-002	Lamictal ODT (lamotrigine) orally disintegrating tablets	November 13, 2009	November 13, 2009
NDA 022115/S-004	Lamictal XR (lamotrigine) extended-release tablets	November 13, 2009	November 13, 2009

We acknowledge receipt of your amendments dated May 5, 2011; May 26, 2011; January 23, 2012; January 24, 2012; May 7, 2012; August 27, 2012; October 11, 2012; October 12, 2012; February 21, 2014; February 24, 2014; February 27, 2014; May 6, 2014; August 25, 2014; and December 5, 2014.

These "Prior Approval" supplemental new drug applications provide for revisions to the Highlights, Drug Interactions, Use in Specific Populations, and Clinical sections of the package insert.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Stephanie N. Parncutt, MHA, Regulatory Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

ERIC P BASTINGS
12/30/2014