NDA 020241/S-068
NDA 020764/S-061
NDA 022115/S-033
NDA 022251/S-032
NDA 020241/S-069
NDA 020764/S-062
NDA 022115/S-034
NDA 022251/S-033

SUPPLEMENT APPROVAL

GlaxoSmithKline LLC
Attention: Linda Rebar
Director, Global Regulatory Affairs
1250 South Collegeville Road
PO Box 5089, Mail Code UP4400
Collegeville, PA 19426-0989

Dear Linda Rebar:

Please refer to your supplemental new drug applications (sNDAs), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number/Supplement Number	Product Name	Date of Submission	Date of Receipt
NDA 020241/S-068	Lamictal (lamotrigine) Tablets	April 10, 2025	April 10, 2025
NDA 020764/S-061	Lamictal (lamotrigine) Tablets for Oral Suspension	April 10, 2025	April 10, 2025
NDA 022115/S-033	Lamictal XR (lamotrigine) Extended-Release Tablets	April 10, 2025	April 10, 2025
NDA 022251/S-032	Lamictal ODT (lamotrigine) Orally Disintegrating Tablets	April 10, 2025	April 10, 2025
NDA 020241/S-069	Lamictal (lamotrigine) Tablets	April 11, 2025	April 11, 2025

NDA 020764/S-062	Lamictal (lamotrigine) Tablets for Oral Suspension	April 11, 2025	April 11, 2025
NDA 022115/S-034	Lamictal XR (lamotrigine) Extended-Release Tablets	April 11, 2025	April 11, 2025
NDA 022251/S-033	Lamictal ODT (lamotrigine) Orally Disintegrating Tablets	April 11, 2025	April 11, 2025

These Prior Approval sNDAs provide for the addition of photosensitivity reaction to Section 6.3 (Adverse Reactions; Postmarketing Experience), and for revisions to the Boxed Warning, Section 5.1 (Warnings and Precautions; Serious Skin Rashes), and the Medication Guide pertaining to an increased risk of serious skin reactions in patients with the genetic variant Human Leukocyte Antigen (HLA)-B*1502 allele. In addition, these supplements provide for the addition of information regarding disease-associated maternal and/or embryofetal risk to Section 8.1 (Use in Specific Populations; Pregnancy).

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

Because none of these criteria apply to your supplemental applications, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

You must submit final promotional materials and Prescribing Information, 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 FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in these supplements, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Kelly Ross, Regulatory Health Project Manager via email at Kelly.Ross@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Alice T.D. Hughes, MD
Deputy Director for Safety
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALICE HUGHES
10/10/2025 03:11:48 PM