DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-241/S-010/S-021/S-025/S-026/S-027
NDA 20-764/S-003/S-014/S-018/S-019/S-020

SmithKlineBeecham
d/b/a GlaxoSmithKline
Attn: Elizabeth McConnell, Pharm.D.
Associate Director, Regulatory Affairs, Neurology
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. McConnell:

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

Name of Drug Product	Reference Number	Dated	Received	Provisions of supplement
Lamictal (lamotrigine) Tablets	NDA 20-241/S-027	Feb. 4, 2005	Feb. 7, 2005	Adjunctive treatment of primary generalized tonic-clonic seizures in adults and pediatric patients
Lamictal (lamotrigine) Chewable Dispersible Tablets	NDA 20-764/S-020	Feb. 4, 2005	Feb. 7, 2005	
Lamictal (lamotrigine) Tablets	NDA 20-241/S-010	Feb. 8, 1999	Feb. 9, 1999	Revisions to the **CLINICAL PHARMACOLOGY-Hepatic Disease** and corresponding subsections of **PRECAUTIONS-Use in Patients with Concomitant Illness** and **DOSAGE AND ADMINISTRATION Patients with Hepatic Impairment** to denote the results of a completed study evaluating the pharmacokinetics of lamotrigine in subjects with varying degrees of hepatic dysfunction. 2. Revisions to the "Hypersensitivity Reactions" and "Acute Multiorgan Failure" subsections of the **WARNINGS**
Lamictal (lamotrigine) Chewable Dispersible Tablets	NDA 20-764/S-003	Feb. 8, 1999	Feb. 9, 1999	

				section based on the October 2, 1998 conference call with the Agency regarding a spontaneous report of a patient whose hepatic dysfunction persisted despite discontinuation of lamotrigine. 3. Revisions to the **OVERDOSAGE-Human Overdose Experience** section based upon your review of spontaneous reports of overdose.
Lamictal (lamotrigine) Tablets	NDA 20-241/S-021	May 29, 2003	May 30, 2003	CBE: Revised wording under PRECAUTIONS: Dermatological Effects, DOSAGE AND ADMINISTRATION, Patient Information, and CLINICAL PHARMACOLOGY: Mechanism of Action
Lamictal (lamotrigine) Chewable Dispersible Tablets	NDA 20-764/S-014	May 29, 2003	May 30, 2003	
Lamictal (lamotrigine) Tablets	NDA 20-241/S-025	June 29, 2004	June 30, 2004	CBE: Revised wording under CLINICAL PHARMACOLOGY: Drug Interactions, PRECAUTIONS: Drug Interactions, and DOSAGE AND ADMINISTRATION
Lamictal (lamotrigine) Chewable Dispersible Tablets	NDA 20-764/S-018	June 29, 2004	June 30, 2004	
Lamictal (lamotrigine) Tablets	NDA 20-241/S-026	Aug. 20, 2004	Aug. 23, 2004	CBE: Revised Patient Information leaflet
Lamictal (lamotrigine) Chewable Dispersible Tablets	NDA 20-764/S-019	Aug. 20, 2004	Aug. 23, 2004	

We acknowledge receipt of your submissions dated February 19, 1999, October 6, 2000, August 11, 2004, May 27, 2005, April 11, 2005, August 31, 2005, and March 22, 2006.

Your submission of March 22, 2006 to the above supplements constituted a complete response to our October 3, 2002 and December 7, 2005 action letters. We acknowledge, as noted in your March 22, 2006 submission, that your response to the [(b)(4) ---------- ------] portion of the action letter is pending.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 20-241/S-010/S-021/S-025/S-026/S-027** and **NDA 20-764/S-003/S-014/S-018/S-019/S-020**." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Courtney Calder, PharmD, Regulatory Project Manager, at (301) 796-1050.

Sincerely,

{See appended electronic signature page}

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

Enclosure