



NDA 21-035/S-050/S-054

NDA 21-505/S-009

UCB, Inc.

Attention: Linda F. Noa, M.S., RAC
Senior Associate, Global Regulatory Affairs
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Ms. Noa:

Please refer to your supplemental new drug applications dated October 17, 2005, and March 31, 2006, received October 18, 2005, and April 3, 2006, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keppra (levetiracetam) tablets and oral solution.

We acknowledge receipt of your submissions dated:

February 14, 2006	March 23, 2006	April 4, 2006
June 28, 2006	August 10, 2006	

These supplemental new drug applications provide for the use of Keppra (levetiracetam) for adjunctive therapy of myoclonic seizures in adults and adolescents age 12 and over with juvenile myoclonic epilepsy and the addition of new adverse events based on post-marketing reports.

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 supplement NDA 21-035/S-050, S-054 and NDA 21-505/S-009.**" 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 are deferring submission of additional pediatric studies until 2011.

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Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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

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

/s/

Russell Katz

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