DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-872/S-005

UCB, Inc.
Attention: Linda Noa, M.S., R.A.C.
Manager, Regulatory Affairs
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Ms. Noa:

Please refer to your supplemental new drug applications dated October 16, 2006 and November 16, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keppra® (levetiracetam) Injection.

We acknowledge receipt of your submission dated October 22, 2007.

Supplemental new drug application NDA 21-872/S-005 provides for the use of Keppra® (levetiracetam) Injection for use as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 16 years of age and older with idiopathic generalized epilepsy.

We have completed our review of this application, as amended and it is 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).

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 this submission "**FPL for approved supplement NDA 21-872/S-005**." Approval of this submission by FDA is not required before the labeling is used.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.
We are waiving the pediatric study requirement for ages birth to 6 years and deferring pediatric studies for ages 6 to 16 years for this application. We note that you already have efficacy studies, using an oral formulation, for ages 6 to 16 years of age. All that would now be required to meet PREA requirements would be a PK bridging and safety study for ages 6 to 16 years old. This can be fulfilled by the study

that you have already committed to conduct: i.e. the pharmacokinetic/safety study in 30 pediatric patients ages four to 16 years (see above). The final report for this study is to be submitted by June 2010.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is noted above.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

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

Enclosure labeling

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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