DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-872/S-002 and 003
NDA 21-035/S-062
NDA 21-505/S-015

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, Tablets and Oral Solution.

We acknowledge receipt of your submissions dated December 22, 2006, and January 12, February 14, August 17 and September 12, 2007.

Supplemental new drug application NDA 21-872-S-003 provides for the use of Keppra® (levetiracetam) Injection for use as adjunctive therapy in the treatment of myoclonic seizures in adults with juvenile myoclonic epilepsy.

NDA 21-035/S-062, NDA21-505/S-015, and NDA 21-872/S-002 are "Changes Being Effected" supplemental new drug applications that provide for the addition of "hepatic failure" to the *Adverse Reactions – Postmarketing* section of the package insert.

We completed our review of the above applications, as amended and they 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).

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 21-872/S-002, S-003, NDA 21-035/S-062, and NDA 21-505/S-015**." 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 waiving the pediatric study requirement for NDA 21-872/S-003.

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 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: Full Prescribing Information

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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