DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-035/S-040
NDA 21-505/S-007

UCB Pharma, Inc.
Attention: Mary D. Alonso
Associate Director, Regulatory Affairs
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Ms. Alonso:

Please refer to your supplemental new drug applications dated December 20, 2004, received December 21, 2004 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 additional submissions dated February 11, 2005, April 15, 2005, April 19, 2005, May 13, 2005, May 26, 2005, June 7, 2005, and June 9, 2005 .

These supplemental new drug applications provide for the use of Keppra (levetiracetam) tablets and oral solution as adjunctive therapy in the treatment of partial onset seizures in children 4 years of age and older with epilepsy.

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 package insert and text for 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-040, NDA 21-505/S-007**." Approval of these submissions by FDA is not required before the labeling is used.

Pediatric Studies

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 your pediatric studies for ages 1 month to 4 years until June 30, 2009.

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. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of partial onset seizures in pediatric patients ages 1 month to 4 years.

   Final Report Submission: June 30, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

Postmarketing Study Commitments

We remind you of your postmarketing study commitment in your submission dated June 21, 2005. This commitment is listed below.

2. Perform a definitive QT/QTc study in healthy adults in accordance with ICH E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (June 2004).

Protocol Submission:	by 12/05
Study Start:	by 03/06
Final Report Submission:	by 12/06

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

Dear Healthcare Professional Letter

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Promotional Materials

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 inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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 Courtney Calder, Pharm.D., Regulatory Project Manager, at (301) 594-5528.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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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