DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-285 **NDA APPROVAL**

UCB, Inc.
Attention: Linda Noa, M.S., RAC
Regulatory Affairs Manager
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms. Noa:

Please refer to your new drug application (NDA) dated November 13, 2007, received November 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Keppra XR™ (levetiracetam) Extended-Release Tablets, 500 mg.

We acknowledge receipt of your submissions dated November 29, and December 19, 2007 and February 15, March 11, 21, and 28, May 8, June 19 and 30, July 15 and 18, August 15, and September 10, 11, and 12, 2008.

This new drug application provides for the use of Keppra XR™ (levetiracetam) Extended-Release Tablets indicated for adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with 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 enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-285."

CARTON AND IMMEDIATE CONTAINER LABELS

Please refer to your submission dated June 19, 2008, containing draft container and carton labeling. We further refer to the September 12, 2008, electronic mail from Ms. Daugherty of this Division, in which the Agency's container and carton labeling recommendations were conveyed. We note that UCB, Inc. has agreed to these recommendations in a subsequent electronic mail from Ms. Noa of UCB, Inc.

Submit final printed carton and container labels revised per the September 12, 2008 electronic communication as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-285**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with final printed labels that are not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENT

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 0 to 12 years because Keppra XR is not an appropriate formulation for that age group and Keppra is currently available in oral solution, which can be used for the pediatric population ages 0 to 12 years. We are deferring submission of your pediatric studies for ages 12 to 16 years because the drug is ready for approval for use in adults and the pediatric studies are not adequate.

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

1. Conduct an open label, single dose, pharmacokinetic study with Keppra XR in patients with epilepsy, ages 12-16 years, in comparison to adult patients with epilepsy. The patient population can presently be receiving Keppra. The pharmacokinetic study would include at least 6 pharmacokinetic samples. The comparison group will be an equal number of adult patients studied under the same conditions.

   For each group (adolescents and adults), the mean Cmax and AUC must be estimated with a standard error of 20% or less, and this would be the basis for the original sample size calculation. As study data are evaluated, the sample size can be re-assessed if necessary for precise estimation of these pharmacokinetic parameters.

Protocol Submission:	by 05/09
Study Start:	by 09/09
Final Report Submission:	by 09/12

Submit all final study reports to your NDA 22-285. Use the following designator to prominently label all submissions:

Required Pediatric Assessment(s)

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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

9/12/2008 04:04:24 PM