CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-872

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-872

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 new drug application (NDA) dated December 20, 2004, received December 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keppra (levetiracetam) 100mg/ml Injection.

We acknowledge receipt of your submissions dated:
July 20, 2005 April 19, 2005 July 6, 2005 August 1, 2005 August 23, 2005
September 15, 2005 October 24, 2005 November 2, 2005 November 3, 2005
November 4, 2005 December 14, 2005 December 21, 2005 December 22, 2005
January 16, 2006 January 31, 2006 March 31, 2006 May 3, 2006 June 13, 2006

The January 31, 2006, submission constituted a complete response to our January 20, 2006, action letter.

This new drug application provides for the use of Keppra (levetiracetam) injection for adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy.

We have completed our review of this application, as amended. 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 and immediate container and carton labels). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 ages zero to one month and deferring pediatric studies for ages one month to 16 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. You have currently committed to fulfilling a portion of this commitment in the four to 16 year age range according to the following timeline:

1. Deferred pediatric study under PREA for a pharmacokinetic and safety study in 30 pediatric patients ages four to 16 years.
   Protocol Submission: by 01/31/2007
   Final Report Submission: by 01/31/2009

Specific commitments for studies in patients ages one month to four years will be discussed at a later date.

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

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

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

Sincerely,

{See appended electronic signature page}

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

Enclosures

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
7/31/2006 05:29:00 PM