DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-035/SCF-048

UCB, Inc.
Attention: Anita K. Fauchier
Manager, Global Regulatory Affairs, CMC
1950 Lake Park Drive
Building 2100
Smyrna, GA 30080

Dear Ms. Fauchier:

Please refer to your supplemental new drug application dated September 6, 2005, received September 7, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keppra (levetiracetam) tablets.

We acknowledge receipt of your submission dated December 6, 2005.

This supplemental new drug application provides for an alternate drug product manufacturing process (b)(4) with new formulation for all strengths), an additional dosage strength (1000 mg tablet) and a name change for the alternate packaging site from (b)(4) to UCB Manufacturing, Inc.

We have completed our review of this application, as amended. This application 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 submitted labeling (package insert, patient package insert, and immediate container and carton labels submitted September 6, 2005).

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 21-035/SCF-048**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the following commitments:

Excipient sources will be qualified according to the respective USP monograph. Future changes to European Pharmacopoeia (EP) excipient monographs will be reported via the annual report route.

Tentative expiration dating will be set at 18 months for the (b)(4) packaging configuration.

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
Food and Drug Administration
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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 R. Calder, Pharm.D., Regulatory Project Manager, at (301) 796-1050.

Sincerely,

{See appended electronic signature page}

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

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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