**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-035

UCB Pharma, Inc.
Attention: Patricia A. Fritz
Director, Regulatory Affairs
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms. Fritz:

Please refer to your correspondence dated October 24, 2001, requesting changes to FDA's August 21, 2001, Written Request for pediatric studies for levetiracetam.

We reviewed your proposed changes and are amending the below listed section of the Written Request. All other terms stated in our Written Request issued on August 21, 2001 remain the same.

**Age group in which studies will be performed:**

For study 1, sufficient number of patients (a minimum of 6 patients in each of the age ranges of 1 month to 2 years, 2 to 6 years, 6 to 12 and 12 to 16 years for a traditional pharmacokinetic study) should be enrolled to sufficiently characterize the pharmacokinetics of levetiracetam. If a population pharmacokinetics approach is utilized an appropriate number of patients should be selected.

Reports of the studies that meet the terms of the Written Request dated August 21, 2001, as amended by this letter must be submitted to the Agency on or before June 5, 2006, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY"** in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a new drug application (NDA) / supplement to an approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Melina Fanari, R.Ph., Senior Regulatory Management Officer, at (301) 594-5526.

Sincerely,

*{See appended electronic signature page}*

Rachel Behrman, M.D.
Deputy Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Rachel Behrman

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