



NDA 21-035/SLR 013 & 019

UCB Pharma, Inc.  
Attention: Patty Fritz  
1950 Lake Park Drive  
Smyrna, GA 30080

Dear Ms. Fritz:

Please refer to your supplemental new drug applications S-013 & 019 for Keppra™ (levetiracetam) Tablets.

These "Changes Being Effected" supplemental new drug applications provide for:

1. A new section in labeling entitled "Postmarketing Experience" which reads as follows:

In addition to the adverse experiences listed above, the following have been reported in patients receiving marketed Keppra worldwide. The listing is alphabetized: leukopenia, neutropenia, pancytopenia and thrombocytopenia. These adverse experiences have not been listed above, and data are insufficient to support an estimate of their incidence or to establish causation.

2. The addition of the terms "aggression, anger, and irritability" to the Warnings, Neuropsychiatric Adverse Events section of labeling.
3. New wording (to replace the existing wording) under the "Nursing Mothers" section of labeling which reads as follows:

Levetiracetam is excreted in breast milk. Because of the potential for serious adverse reactions in nursing infants from Keppra, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

As a suggestion to better characterize the potential risks to nursing infants from mothers taking Keppra and the milk/plasma ratio, we recommend a future study that compares serum and breast milk concentrations with repeat measures of each over an extended period of time (2 days).

Food and Drug  
Administration  
Rockville MD 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

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

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/s/

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Russell Katz  
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