



NDA 21035/S-052/S-073/S-074/S-083/S-085
NDA 21505/S-019/S-020/S-025/S-026

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Heather Forusz, Ph.D.
Senior Manager, Regulatory Affairs
1950 Lake Park Drive, Building 2100
Smyra, GA 30080

Dear Dr. Forusz:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

| Application | Drug Product | Submitted on: | Received on: |
|--|--------------------------------|---------------|--------------|
| NDA 21035/S-052 | Keppra (levetiracetam) Tablets | 12/20/2005 | 12/21/2005 |
| This "Prior Approval" supplement provides for: | | | |
| Revisions to the "Carcinogenesis" section of labeling to update information regarding a 2 year oral mouse carcinogenicity study. | | | |

| Application | Drug Product | Submitted on: | Received on: | Amended on: |
|--|--------------------------------------|---------------|--------------|---|
| NDA 21035/S-073 | Keppra (levetiracetam) Tablets | 3/18/2008 | 3/19/2008 | 6/20/2011 8/5/2011 8/16/2011 10/13/2011 12/1/11 |
| NDA 21505/S-019 | Keppra (levetiracetam) Oral Solution | 3/18/2008 | 3/19/2008 | 6/30/2011 8/5/2011 8/16/2011 12/1/2011 |
| These "Prior Approval" supplements provide for: | | | | |
| Use of Keppra tablets and oral solution as adjunctive therapy in the treatment of partial onset seizures in children 1 month to less than 4 years. | | | | |

| Application | Drug Product | Submitted on: | Received on: |
|--|--------------------------------------|---------------|--------------|
| NDA 21035/S-074 | Keppra (levetiracetam) Tablets | 7/1/2008 | 7/2/2008 |
| NDA 21505/S-020 | Keppra (levetiracetam) Oral Solution | | |
| These “Changes Being Effected” supplements provide for: | | | |
| Addition of information regarding seizure control during pregnancy and decreased levetiracetam drug levels to the “WARNINGS AND PRECAUTIONS” and “Pregnancy” sections of labeling. | | | |

| Application | Drug Product | Submitted on: | Received on: |
|---|--------------------------------------|---------------|--------------|
| NDA 21035/S-083 | Keppra (levetiracetam) Tablets | 7/17/2009 | 7/20/2009 |
| NDA 21505/S-025 | Keppra (levetiracetam) Oral Solution | | |
| These “Prior Approval” supplements provide for: | | | |
| Updating the content of labeling consistent with the <i>Guidance for Industry: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products</i> issued in January 2006. | | | |

| Application | Drug Product | Submitted on: | Received on: | Amended on: |
|--|--------------------------------------|---------------|--------------|-------------|
| NDA 21035/S-085 | Keppra (levetiracetam) Tablets | 4/2/2010 | 4/5/2010 | 6/25/2010 |
| NDA 21505/S-025 | Keppra (levetiracetam) Oral Solution | | | |
| These “Changes Being Effected” supplements provide for: | | | | |
| Addition of information regarding serious skin rash to the “WARNINGS AND PRECAUTIONS” section of labeling and to the Medication Guide. | | | | |

We note that your June 20, 2011 submission to NDA 21035/S-073 and June 30, 2011 submission to NDA 21505/S-019 constituted a complete response to our June 2, 2010 action letter.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 21 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 30 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

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 1 month because necessary studies are impossible or highly impracticable. This is because few patients are diagnosed with this disorder in this age group.

This product is appropriately labeled for use in ages 5 years to 16 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 1 month to 4 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Jacqueline H. Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

Content of 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 G KATZ
12/16/2011