



NDA 21259/S-023/S-024

**SUPPLEMENT APPROVAL**

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

Dear Dr. Forusz:

Please refer to your Supplemental New Drug Applications (sNDA) dated February 17, 2012 (21259/S-023), and May 4, 2012 (21259/S-024), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Metadate CD (methylphenidate HCl) Extended-Release Capsules 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg.

We acknowledge receipt of your amendment dated July 26, 2012.

Reference is also made to an Agency letter dated August 17, 2011, requesting that you conduct an adequate *in vitro* performance study and submit proposed labeling as a labeling supplement incorporating the results of the study.

These supplemental new drug applications propose the following revisions to product labeling.

**21259/S-023 (submitted as a “Prior Approval” supplemental new drug application)**

1. Addition of a new subsection entitled Alcohol Effect in the **Clinical Pharmacology** section.
2. Revisions to the **PRECAUTIONS-Information for Patients**, and **Dosage and Administration** sections regarding consumption of alcohol.
3. Revisions to the Medication Guide.

**21259/S-024 (submitted as a “Changes Being Effected” supplemental new drug application)**

- The addition of the term “bruxism” in the **Adverse Reactions-Postmarketing Experience** section.

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.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 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, and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, 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).

## **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, email Shin-Ye Sandy Chang, Regulatory Project Manager, at [shinye.chang@fda.hhs.gov](mailto:shinye.chang@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, M.D.  
CAPT, USPHS  
Director (acting)  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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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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MITCHELL V Mathis  
05/06/2013