DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-259/S-021

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

Dear Ms. Forusz:

Please refer to your supplemental new drug application dated September 30, 2008 received October 1, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metadate CD (methylphenidate HCl, USP) 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg Extended-Release Capsules.

This "Changes Being Effected" supplemental new drug application provides for changes to the Adverse Reactions and Reference sections of the labeling.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the submitted and enclosed labeling text.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Terry Harrison, Regulatory Project Manager, at Terry.Harrison@FDA.HHS.GOV

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (Labeling)

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

/s/

Thomas Laughren
4/16/2009 04:13:09 PM