DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-259 / S-019

UCB, Inc.
Attention: Jennifer Brown
Manager, Labeling, Promotion, and Advertising
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Ms. Brown:

Please refer to your supplemental new drug application dated March 30, 2007, received April 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metadate CD (methylphenidate HCl, USP) Extended-Release Capsules.

This "Changes Being Effected" supplemental new drug application provides for changes to the Contradictions, Warnings, Precautions, Adverse Reactions, and Drug Abuse and Dependence sections of the labeling.

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

We note your March 30, 2007 submission of the content of the labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format. The final printed labeling (FPL) must be identical to the enclosed labeling. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-9259 / S-019.**" Approval of these submissions by FDA is not required before the labeling is used.

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 CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@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

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
8/26/2008 02:49:37 PM