DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-259/S-017

UCB Pharma, Incorporated
Attention: Mary Evelyn Towne
Manager, Regulatory Affairs
755 Jefferson Road, P.O. Box 31710
Rochester, NY 14603-1710

Dear Ms. Towne:

We acknowledge receipt of your supplemental new drug application dated October 27, 2005, received October 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metadate CD (Methylphenidate HCL) Extended-Release Capsules.

We additionally acknowledge receipt of your amendment dated February 1, 2006.

This supplemental new drug application provides for the following changes:

1. The addition of 40 mg, 50 mg, and 60 mg strengths to the physician labeling as well as the patient package insert.
2. The change of the capsule imprinting on the 10 mg, 20 mg, and 30 mg strengths.
3. The change of the NDC numbers for the 10 mg, 20 mg, and 30 mg strengths.
4. The deletion of blister packaging.
5. The addition of (b)(4) as the supplier of the (b)(4)

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

However, we note that the enclosed labeling also includes changes proposed in your pending "Changes Being Effected" supplemental application (b)(4) submitted August 10, 2005. Please note that this approval does not apply to the changes proposed in the pending supplemental application. We are currently evaluating the pending application and will comment on the changes in a separate action letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert submitted February 1, 2006). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 21-259/S-017**." Approval of this submission by FDA is not required before the labeling is used.

Please amend all pending supplemental application(s) for Metadate CD with labeling that includes the changes approved with this application, 21-259/S-017.

Additionally, please note that we are granting a 24 month Expiration Date for the three new strengths, 40mg, 50mg, and 60 mg.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division, the Division Psychiatry Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Susan Player, Regulatory Project Manager, at (301) 796-1074.

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
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