DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-259/S-008

Celltech Pharmaceuticals, Inc.
Attention: Norma Cappetti
Director, Regulatory Affairs
755 Jefferson Road, P.O. Box 31710
Rochester, NY 14603-1710

Dear Ms. Cappetti:

Please refer to your supplemental new drug application dated May 21, 2003, received May 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metadate® CD (methylphenidate hydrochloride) Extended-release Capsules.

We acknowledge receipt of your amendment dated August 8, 2003.

This supplemental new drug application provides for:

(b)(4)----------

- Addition of Celltech Manufacturing, Inc., Rochester, N.Y., as a manufacturer and test site for the Immediate-release, (b)(4)----------and Extended-release bead components of Metadate® CD Extended-release Capsules
- Addition of Celltech Manufacturing, Inc. as a manufacturer of the 10 mg, 20 mg and 30 mg dosage strengths
- Addition of Celltech Manufacturing, Inc. as a test site for raw materials

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the labeling text dated May 21, 2003. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated May 21, 2003); except for an agreed upon correction to the description of the 30 mg capsule strength as reddish brown/white in the “How Supplied” section.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement “NDA 21-259/S-008". Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please call, Ms. Anne Marie H. Weikel R.Ph., Senior Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz

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