DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-259/S-006

Celltech Pharmaceuticals, Inc.
Attention: Ruta Monoenko
Senior Regulatory Affairs Associate
755 Jefferson Road, P.O. Box 31710
Rochester, NY 14603-1710

Dear Ms. Monoenko:

Please refer to your supplemental new drug application dated February 17, 2003, received February 19, 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 submission dated March 27; May 1 and 16; and June 3 and 12, 2003.

This supplemental new drug application provides for an additional 30 mg dosage strength.

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 agreed upon labeling text dated February 17, 2003. Accordingly, this supplemental application is approved effective on the date of this letter.

Expiration Date

A 24-month expiry is granted for the 30 mg strength based on the stability data provided.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated February 17, 2003) with the recently approved changes for S-005 for the 10 mg strength ('Description', 'Dosage and Administration' and 'How Supplied' sections).

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-006". 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. Anna 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
6/19/03 09:51:56 AM