DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-259/S-001

Celltech Pharmaceuticals, Inc.
Attention: Cheryl Rini, RN
Senior Manager, Regulatory Affairs
755 Jefferson Road
P.O. Box 31710
Rochester, NY 14603-1710

Dear Ms. Rini:

Please refer to your supplemental new drug application dated July 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metadate® CD (methylphenidate HCl, USP) Extended-release Capsules.

We acknowledge receipt of your amendment dated February 1, 2002.

This supplemental new drug application provides for information in the labeling for sprinkling the capsule contents on applesauce for administration. In addition, there are changes to the CLINICAL PHARMACOLOGY section regarding renal and hepatic insufficiency.

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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-259/S-001". 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 Homonnay, R.Ph., Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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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