DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-111/S-011

Celltech Pharmaceuticals, Inc
755 Jefferson Road
P.O. Box 31710
Rochester, NY 14603-1710

Attention: Cheryl A. Rini, R.N.
Senior Manager, Regulatory Affairs

Dear Ms. Rini:

Please refer to your supplemental new drug application dated May 9, 2003, received May 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tussionex Pennkinetic (hydrocodone polistirex/ chlorpheniramine pilistirex).

This "Changes Being Effected" supplemental new drug application provides the addition of a Geriatric Use subsection to the Precautions section of the package insert and the addition of the phrase "(See Warning)" in the Pediatric Use subsection of the Precautions section of the Package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 9, 2003.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 have any questions, call Ladan Jafari , Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
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/

Badrul Chowdhury

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