DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-806/S-008

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

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

Dear Ms. Rini:

Please refer to your supplemental new drug application dated August 20, 2003, received August 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Semprex-D (acrivastine and pseudoephedrine) Capsules.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor revision listed below and agreed to in a telephone conversation on February 25, 2004, between Sandy Barnes of this office and Ruta Monoenko of your company.

> Revise the first sentence of the Geriatric subsection to read "Of the total number of subjects in clinical studies of SEMPREX-D, 349 were 60 years of age or older and 53 were 70 years of age and older.

The final printed labeling (FPL) must be identical, and include the minor revision indicated, to the submitted labeling (package insert submitted August 20, 2003). These revisions are terms of the approval of this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-806/S-008." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 827-9388.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D, Ph.D.
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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