CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-157 / S-018

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-157/S-018

Celltech Pharmaceuticals, Inc.
Attention: Cheryl A. Rini
Senior Manager, Regulatory Affairs
Labeling and Promotions
P.O. Box 31710
Jefferson Road
Rochester, New York 14603

Dear Ms. Rini:

Please refer to your supplemental new drug application 018 dated August 21, 2003, received August 27, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prediapred® (prednisolone sodium phosphate) Oral Solution 6.7 mg/5 mL.

We acknowledge receipt of your submission dated June 03, and 09, 2004.

Your submission of June 03, 2004 constituted a complete response to our February 27, 2003 action letter.

This supplemental new drug application proposes to add information regarding use in a geriatric population to the CLINICAL PHARMACOLOGY section and to add a *Geriatric Use* subsection in the PRECAUTIONS section of the package circular.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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 Barbara Gould, Regulatory Project Manager, at (301) 827-2506.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic, &
Ophthalmic Drug Products
Office of Drug Evaluation V
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/

Sharon Hertz
12/3/04 06:22:43 PM