DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-658/S-017

Celltech Pharmaceuticals, Inc.
Attention: Sean Alan F. X. Reade
Vice President, Regulatory Affairs
755 Jefferson Road
P.O. Box 31710
Rochester, NY 14603-1710

Dear Mr. Reade:

Please refer to your supplemental new drug application dated July 9, 2004, received July 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delsym® (dextromethorphan polistirex) Extended-Release Suspension.

We acknowledge receipt of your submissions dated August 11 and September 30, 2004.

This supplemental new drug application provides for the following:

- addition of ---------- to the formulation
- change to a ---------- ----------
- change to a ----------
- drug product manufacturing process changes - ---------- ----------
  ----
- additional batch size --------- g product manufact
- ---------- ay testing of · --------- ---- ---------- --------- - ---------- throughout the shelf life of the drug product
- carton and container labeling for the 15 mL, 89 mL, and 148 mL packages.

Your supplemental new drug application also requested a waiver of the in vivo bioequivalence requirement (21 CFR 320.21(c)(1)) for the reformulated drug product.

We have completed our review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (89 mL immediate container and carton labeling submitted on July 7, 2004 and the 15 mL and 148 mL immediate container and carton labeling submitted on August 11, 2004).

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-658/S-017." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the word "NEW" on the principal display panel (PDP) after 180 days of marketing.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Project Manager, at (301) 827-2276.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Curtis Rosebraugh

11/10/04 02:57:33 PM