DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-658/S-018

Celltech Pharmaceuticals, Inc.
Attention: Sean Alan 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 August 19, 2004, received August 20, 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 November 3 and 30, and December 28, 2004, and February 10, 2005. Your December 28, 2004, submission constituted a complete response to our December 20, 2004, action letter.

This supplemental new drug application provides for the following:

- an additional container/closure system, i.e. amber polypropylene bottles with a ---------
  polyethylene cap and foam/foil laminate cap liner for the packaging of the fini----------
- weight loss specification for the finished product over shelf-life.

We have completed our review of this supplemental application, as amended. This supplement is 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 draft labeling (15 mL, 89 mL, and 148 mL immediate container and carton labeling submitted on August 19, 2004, with and without the child presentation on the carton principal display panel [PDP]) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-658/S-018**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag “NEW Plastic Bottle” on the 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
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