



NDA 18-658/S-015

Celltech Americas, Inc.
Attention: R. Andrew Morgan, R.Ph.
Director, Regulatory Affairs
755 Jefferson Road
P.O. Box 31710
Rochester, NY 14603-1710

Dear Mr. Morgan:

Please refer to your new supplemental new drug application (NDA) dated May 10, 2000, received on May 15, 2000, 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 September 17 and October 26, 2001. Your submission of September 17, 2001 constituted a complete response to our March 14, 2001, action letter.

This supplemental new drug application provides for revisions to the labeling for the product in accordance with regulatory requirements in the Final Rule published in the Federal Register on May 17, 1999, regarding "Over-the-Counter Human Drugs; Labeling Requirements" (64 FR 13254).

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

The final printed labeling (FPL) must be identical to the draft labeling submitted on September 17, 2001, (package insert, immediate container and carton labels), with the inclusion of the changes proposed in your October 26, 2001, amendment.

Please submit copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. For administrative purposes, this submission should be designated "FPL for approved NDA 18-658." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

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, please call Babette Merritt, Regulatory Health Project Manager, at (301)

827-2252.

Sincerely,

Linda M. Katz, 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

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/s/

Linda Katz

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