DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-658/S-022

Adams Respiratory Therapeutics
Attention: Doreen Frank
Executive Director, Regulatory Affairs
4 Mill Ridge Lane
Mill Ridge Farm
Chester, NJ 07930

Dear Ms. Frank:

Please refer to your supplemental new drug application dated February 23, 2007, received February 26, 2007, submitted pursuant to 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 June 27 and July 19 and 23, 2007. Your submission of July 23, 2007 constituted a complete response to our June 26, 2007 action letter. We also acknowledge receipt of your commitment regarding this supplement dated April 5, 2007, in which you agreed to remove the word "Great" from all of the labeling within 180 days of marketing.

This supplemental application provides for a grape flavored formulation of Delsym Extended-Release Suspension.

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. This application 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 submitted labeling (carton and container labels for the 89- and 148 mL bottles [children and adult SKUs], container label for the 15 mL physician sample, physician sampling tray [children and adult SKUs] submitted on February 23, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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 these submissions "**FPL for approved NDA 18-658/S-022**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitment dated April 5, 2007 to remove the word “Great” from all of the labeling within 180 days of marketing. We also remind you to remove the word “New” from the phrase “New grape flavor” from 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

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