DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-585/S-001

Adams Respiratory Therapeutics
Attention: Susan Witham
Vice President, Regulatory Affairs
425 Main Street, Colonial Court
Chester, NJ 07930

Dear Ms. Witham:

Please refer to your supplemental new drug application dated June 28, 2004, received June 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex D (600/60 mg and 1200/120 mg guaifenesin and pseudoephedrine HCl) Extended-release Bi-layer Tablets.

We acknowledge receipt of your submissions dated September 23, and November 23, 2004.

This supplemental new drug application proposes new alternative blister packaging for the drug product and a new packaging site for the blister packaging.

We have completed our review of this 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 (2-count Sample Blister Card, 6-count Blister Card, 12/2-count Blister Carton Sample Tray, 2-count Sample Blister Carton, 18-count Blister Carton, and 36-count Blister Carton labeling submitted September 23, 2004 for the 600 mg guaifenesin/60 mg pseudoephedrine HCl strength and 6-count Blister Card and 18-count Blister Carton labeling submitted September 23, 2004 for the 1200 mg guaifenesin/120 mg pseudoephedrine HCl strength), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-585/S-001". Approval of this submission by FDA is not required before the labeling is used.

We remind you that the word "NEW" must be deleted wherever it appears on the labeling of the various size SKUs and dispensing trays six months after introduction into the marketplace.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Leah Christl, Ph.D., Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Curtis J. Rosebraugh, M.D., MPH
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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