DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-282/S-016

Adams Respiratory Therapeutics, Inc.
Attention: Toni Ann Dudor
Director, Regulatory Affairs
4 Mill Ridge Lane, Mill Ridge Farm
Chester, NJ 07930

Dear Ms. Dudor:

Please refer to your supplemental new drug application dated September 13, 2006, received September 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex (guaifenesin) Extended Release Bi-Layer Tablets, 1200 mg.

This supplemental new drug application provides for a new trade name, Humibid, and other minor labeling changes for the 20-count bottle size. These changes are for the 20-count container label for the 1200 mg strength only. There is no outer carton with "Humibid" as the trade name for this package size.

We have completed our review of this supplemental application. 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 (bottle labeling submitted September 13, 2006), 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 21-282/S-016**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
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, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
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/

Andrea Segal

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