DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-620/S-005

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 September 26, 2005, received September 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex DM (guaifenesin and pseudoephedrine HCl Extended-release Bi-layer Tablets 600/30 mg).

We acknowledge receipt of your submission dated December 7, 2005.

This supplemental new drug application provides for packaging the 600/30 mg guaifenesin and pseudoephedrine HCl product in foil pouches that will contain two tablets.

We have completed our review of this 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 (2-count sample pouch label and 25 pouch [i.e., 25 counts of 2-count sample pouches] carton label submitted September 26, 2005), 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 21-620/S-005**." Approval of this submission by FDA is not required before the labeling is used.

We recommend use of the same language “Sample” or “Physician’s Samples” on the pouch label and carton label PDP for consistency, preferably “Sample”.

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
WO22, 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}

Andrea Leonard-Segal, M.D.
Acting 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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