DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-620

Adams Respiratory Therapeutics
14841 Sovereign Road
Fort Worth, TX 76155-2645

Attention: Daniel F. Wagner
Director, Clinical and Regulatory Affairs

Dear Mr. Wagner:

Please refer to your June 30, 2003, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex ™DM (guaifenesin and dextromethorphan) Extended-release Tablets.

We acknowledge receipt of your submissions dated July 14, August 14 and 25, and November 3 and 11, 2003, and January 30, February 18 and 27, and March 3, 12, and 25, 2004.

This new drug application provides for the use of Mucinex ™DM (guaifenesin and dextromethorphan HBr) Extended-release Tablets as an expectorant and antitussive.

We completed our review of this application, as amended. It 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 (immediate container, carton, and tray labels submitted March 12, 2004), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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 NDA 21-620**." Approval of this submission by FDA is not required before the labeling is used.

We have the following comments.

1. You have agreed to monitor for adverse events related to Mucinex® DM abuse as outlined in your March 3, 2004, submission. If a safety signal is noted in postmarketing surveillance, you have agreed to devise and implement a risk management plan to reduce rates of abuse of Mucinex® DM. If a safety signal is detected, you should consider whether the drug product should be placed behind the pharmacy counter to deter individuals from purchasing large quantities at one time.

2. The word "NEW" must be deleted from the PDP six months after introduction into the market place.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for patients less than 12 years of age for this application.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Pulmonary and Allergy Drug Products and the other copy, along with the labeling, to Division of Over-the-Counter Drug Products, HFD-560.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, call Leah Cutter, Ph.D., Regulatory Project Manager at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure Approved labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
4/28/04 03:26:40 PM

Charles Ganley
4/29/04 03:57:18 PM