DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-585

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 new drug application (NDA) dated January 31, 2003, received January 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex ™D (guaifenesin and pseudoephedrine HCl) Extended-release Tablets, 1200mg/120mg and 600mg/60mg.

We acknowledge receipt of your submissions dated April 30, June 30 (2), July 14, August 18 (2), September 5 and 19, October 17 and 27, November 4, and December 19, 2003, and February 17 and 25, April 9, and May 6, 2004.

The December 19, 2003, submission constituted a completed response to our November 24, 2003, action letter.

This new drug application provides for the use of Mucinex ™D (guaifenesin and pseudoephedrine HCl) Extended-release Tablets as an expectorant and nasal decongestant.

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 February 25, 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.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format (pdf) effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that the labeling content must be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. Approval of this submission by FDA is not required before the labeling is used.

We have the following comment.

> 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.

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 Elaine Abraham, Regulatory Project Manager at (301) 827-2276.

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
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Curtis Rosebraugh
6/22/04 02:38:36 PM