



NDA 21-282/S-011

Adams Respiratory Therapeutics  
Attention: Susan Witham  
Vice President, Regulatory Affairs  
4 Mill Ridge Lane, Mill Ridge Farm  
Chester, NJ 07930

Dear Ms. Witham:

Please refer to your supplemental new drug application dated February 21, 2006, received February 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex (guaifenesin) Extended Release Bi-Layer Tablets, 600 and 1200 mg.

We acknowledge receipt of your submissions dated March 9 and 22, 2006.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for a new 100-count bottle size and a new trade name, Humabid. Both changes are for the 1200 mg strength only.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 21, 2006.

After 180 days from the launch date (i.e. March 2006), we remind you to remove the following from the principal display panel:

- 1) The word "New"
- 2) The phrase "MAXIMUM STRENGTH" because there is no lower strength "Humabid".

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 set forth under 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

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/s/

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Andrea Segal  
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