



NDA 21-585/S-002

NDA 21-620/S-001

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 applications dated July 30, 2004, received August 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex D (600/60 mg and 1200/120 mg guaifenesin and pseudoephedrine HCl) Extended-release Bi-layer Tablets and Mucinex DM (600/30 mg and 1200/60 mg guaifenesin and dextromethorphan) Extended-release Bi-layer Tablets.

We acknowledge receipt of your submissions dated September 24 (both), October 19 (NDA 21-585), and October 20, 2004 (NDA 21-620).

These "Changes Being Effected in 30 days" supplemental new drug applications provide for packaging both strengths of Mucinex D and Mucinex DM in two additional sizes: 100-count and 500-count bottles.

We have completed our review of these applications, as amended. These applications are 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 labels submitted October 19, 2004 for the Mucinex D drug product and October 20, 2004 for the Mucinex DM drug product), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-585/S-002" and "FPL for approved supplement NDA 21-620/S-001", respectively. Approval of these submissions by FDA is not required before the labeling is used.

We remind you that the word "NEW" must be deleted from the PDP six months after introduction into the marketplace.

NDA 21-585/S-002

NDA 21-620/S-001

Page 2

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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

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

Sincerely,

*{See appended electronic signature page}*

Curtis J. Rosebraugh, M.D.  
Deputy Director  
Division of Over-the-Counter Drug Products  
Office of Drug Evaluation V  
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/

-----  
Curtis Rosebraugh  
1/24/05 12:30:59 PM