



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-282/S-021
NDA 21-585/S-012
NDA 21-620/S-011

Adams Respiratory Therapeutics
Attention: Doreen Frank
Executive Director, Regulatory Affairs
4 Mill Ridge Lane
Mill Ridge Farm
Chester, NJ 07930

Dear Ms. Frank:

Please refer to your supplemental new drug applications dated March 7, 2007, received March 8, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex (600 and 1200 mg guaifenesin) extended release bi-layer tablets [NDA 21-282/S-021], Mucinex® D (600 mg guaifenesin/60 mg pseudoephedrine HCl and 1200 mg guaifenesin/120 mg pseudoephedrine HCl) extended-release bi-layer tablets [NDA 21-585/S-012], and Mucinex® DM (600 mg guaifenesin/30 mg dextromethorphan HBr and 1200 mg guaifenesin/60 mg dextromethorphan HBr) extended-release bi-layer tablets [NDA 21-620/S-011].

We acknowledge receipt of your submissions dated April 5 and May 31, 2007.

These "Changes Being Effected" supplemental new drug applications provide for the phrase "Maximum Strength" to be added to the label for the 1200 mg guaifenesin strength formulations for all three products as well as to change the tablet color for all three products to the same dye used in their respective 600 mg guaifenesin strength formulations.

We have completed our review of these supplemental 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 (14- and 28-count carton and bottle labeling [NDA 21-282/S-021 and NDA 21-620/S-011] and 24-count carton and 6-count blister card labeling [NDA 21-585/S-012] submitted May 31, 2007) 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 these submissions "**FPL for approved supplements NDA 21-282/S-021, NDA 21-585/S-012, and**

NDA 21-620/S-011.” Approval of these submissions by FDA is not required before the labeling is used.

We remind you to remove the flag “NEW!” from the principal display panel (PDP) after 180 days of marketing.

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 these NDAs 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 (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}

Joel Schiffenbauer, M.D.
Deputy 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/

Joel Schiffenbauer

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