DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-282/S-001

Adams Laboratories, Inc.
Attention: D. Jeffrey Keyser
Vice President, Development & Regulatory Affairs
14801 Sovereign Road
Fort Worth, TX 76155

Dear Mr. Keyser:

Please refer to your supplemental new drug application dated August 27, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex (guaifenesin) Extended Release Tablet, 1200 mg.

We acknowledge receipt of your submissions dated December 11, 13, and 16 (fax), 2002.

This supplemental new drug application provides for a new dosage strength, 1200 mg tablet, in 30cc/2 count, 75 cc/10 count and 75 cc/20 count HDPE bottles.

We have completed our review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (immediate container and carton labels) submitted on August 27, 2002.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-282/S-001." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
FDA
5600 Fishers Lane
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, R.Ph., Regulatory Project Manager, at (301) 827-2301.

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

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

/s/

Charles Ganley

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