DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-282/S-029

Reckitt Benckiser
Attention: Douglas Flint
Manager, Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Flint:

Please refer to your supplemental new drug application dated December 1, 2008, received December 5, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mucinex® (guaifenesin 600 mg and 1200 mg) Extended-Release Bi-Layer tablets.

We acknowledge receipt of your amendment dated February 17, 2009.

This supplemental new drug application provides for the following changes to the Mucinex® 600 mg product:

1. the packaging of the tablets in blisters;
2. a change in tablet shape from round to modified oval;
3. a change in debossing of the modified release (MR) layer from "A" to "RB";
4. a reduction in [redacted]
5. an [redacted]; and
6. the elimination of [redacted] testing.

We have completed our review of this application, as amended. This application 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 enclosed labeling (10-count blister card submitted on December 1, 2008 and the 20-count carton label submitted on February 17, 2009 for Mucinex® (guaifenesin 600mg) extended-release bi-layer tablets), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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 this submission "**FPL for approved supplement NDA 21-282/S-029**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the two flags, "NEW LOOK – SAME RELIEF" and "NEW OVAL TABLET," from the principal display panel after six months 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 this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

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

Enclosure

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

/s/

Andrea Segal

4/3/2009 10:18:57 AM