DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021282/S-048

SUPPLEMENT APPROVAL

Reckitt Benckiser LLC
Attention: Shavina Mehre, PharmD
Regulatory Lead/Strategy Lead, CMC
399 Interpace Parkway
Parsippany, NJ 07054

Dear Dr. Mehre:

Please refer to your Supplemental New Drug Application (sNDA) dated January 3, 2017, received January 4, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex (guaifenesin) 600 mg tablets, and Maximum Strength Mucinex (guaifenesin) 1200 mg tablets.

This "Changes Being Effected" supplemental new drug application provides for authorized generic versions of the approved Mucinex products and proposes the following:

- Add new packaging site
- Remove dye
- Change debossing

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

The tamper evident statement is in bold font in the Drug Facts portion of your labeling. Revise the font for this statement from bold to normal font and submit updated labels in your final printed labeling submission.

As authorized generic drug products (as defined in § 314.3) distributed under NDA 021282, we remind you of the annual postmarketing reporting requirements in § CFR 314.81, and in particular, section *Authorized Generic Drugs* in § 314.81(b)(2)(ii)(b).

We remind you that the relabeled product's label and labeling must be identical to the application holder's label and labeling, with the exception of trade dress and required manufacturer, packer, or distributor information as applicable under 21 CFR 201.1. It is the responsibility of the application holder to ensure that all labeling of the relabeled product is identical, with the exceptions noted, to the labeling approved under the NDA.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the submitted labeling listed in the table below, with the minor editorial revision listed above, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date submitted
14-ct and 28-ct 1200 mg outer containers	1/4/17
20-ct and 40-ct 600 mg outer containers	1/4/17
14-ct 1200 mg immediate container (blister pack)	6/28/17
20-ct 600 mg immediate container (blister pack)	6/28/17

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021282/S-048**". Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

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

/s/

THERESA M MICHELE
07/03/2017