DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21620/S-39

SUPPLEMENT APPROVAL

Reckitt Benckiser LLC
Attention: Punam Desai
Senior Regulatory Manager, CMC
399 Interpace Parkway
Parsippany, NJ 07054-0225

Dear Ms. Desai:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 3, 2018 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex DM (guaifenesin 600 mg and dextromethorphan HBr 30 mg) extended release tablets.

This "Changes Being Effected" supplemental new drug application provides for addition of an alternative packaging site, deletion of an inactive ingredient, and change to existing deboss for an authorized generic product.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We remind you that the authorized generic product 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 authorized generic product is identical, with the exceptions noted, to the labeling approved under the NDA.

LABELING

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date submitted
20-ct and 40-ct outer containers	7/3/18
20-ct blister pack	7/3/18

The FPL 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 (April 2017, Revision 4).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21620/S-39**." 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.

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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
01/03/2019 10:08:19 AM