



NDA 021585/S-033  
NDA 021620/S-038

**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 Applications (sNDAs) dated January 16, 2017, received January 17, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following drug products:

- NDA 21585/S-033: Mucinex D (guaifenesin 600 mg and pseudoephedrine HCl 60 mg) extended release tablet
- NDA 21620/S-038: Mucinex DM (guaifenesin 1200 mg and dextromethorphan HBr 60 mg) extended release tablets

These “Changes Being Effected” sNDAs propose the following changes:

- Add new packaging site
- Remove <sup>(b) (4)</sup>
- Change debossing

We have completed our review of these applications, as amended. They are 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 21 CFR 314.3) distributed under NDA 021585 and NDA 021620, we remind you of the annual postmarketing reporting requirements in § 314.81, and in particular, section *Authorized Generic Drugs* in § 314.81(b)(2)(ii)(b).

We remind you that the relabeled products’ 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 products are identical, with the exceptions noted, to the labeling approved under the NDAs.

### **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.

<b>NDA 21585/S-033 - Submitted Labeling</b>	<b>Date submitted</b>
18-ct and 36-ct outer containers	1/17/17
18-ct immediate container (blister pack)	6/28/17

<b>NDA 21620/S-038 - Submitted Labeling</b>	<b>Date submitted</b>
14-ct and 28-ct outer containers	1/17/17
14-ct 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 021585/S-033**” or “**Final Printed labeling for approved NDA 021620/S-038**” as appropriate. Approval of these submissions 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.

## **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 applications, 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  
07/13/2017