NDA 21282/S-54
NDA 21620/S-43

SUPPLEMENT APPROVAL

RB Health (US) LLC
Attention: Ebru Unver Kulak
Senior Regulatory Manager
399 Interpace Parkway
Parsippany, NJ 07054-0225

Dear Ms. Kulak:

Please refer to your supplemental new drug applications (sNDAs) dated and received August 21, 2020 and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

> NDA 21282/S-54: Mucinex (guaifenesin 600 mg) and Maximum Strength Mucinex (guaifenesin 1200 mg) extended-release tablet
>
> NDA 21620/S-43: Mucinex-DM (guaifenesin 600 mg and dextromethorphan HBr 30 mg) and Maximum Strength Mucinex-DM (guaifenesin 1200 mg and dextromethorphan HBr 60 mg) extended-release tablet

These sNDAs were submitted in response to Supplement Request Letters sent by the Agency on July 17, 2020.

APPROVAL & LABELING

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 enclosed agreed-upon labeling with the agreed-upon editorial revisions listed below:

For enclosed labeling that has not been revised as of the date of this letter, make the following revisions, in accordance with your commitment in the amendment to this supplement dated February 1, 2021:

For all labeling:

Carton Labeling:

- Remove the term “bi-layer” from the statement of identity and the declaration of net quantity of contents, and wherever it appears on the outer container labeling (including the Principal Display Panel (PDP), top, back and side panels), on all carton and folder/sample bin labels. However, we do not object to its use next to

the depiction of the actual tablet on the side panel. “Bi-layer” is not a dosage form term recognized by USP. According to the USP nomenclature guidelines, the correct dosage form for the product is “extended-release tablet”.

- Revise all tablet images on the labeling to depict the true size, color, and imprint of the actual tablet.

Drug Facts:

- Revise “Active ingredient (in each extended-release bi-layer tablet)” to “Active ingredient (in each extended-release tablet)” so that all dosage form nomenclature is consistent with the drug product’s stated dosage form (i.e., extended-release tablet).

- Under the Directions heading, revise the dosage form to “extended-release tablet” so that all dosage form nomenclature is consistent with the drug product’s stated dosage form (i.e., extended-release tablet).

Immediate Container (Blister) Label:

- Remove the term “bi-layer”. This is not a dosage form term recognized by USP, as noted above.

Additionally, for the following specific labels:

NDA 21282/S-54

Mucinex (600 mg guaifenesin) 20-Count Outer Container (Folder and Sample Tray) Labels:

- Add the statement of identity (SOI) under the proprietary name. The SOI should be written as “600 mg guaifenesin, extended-release tablets, expectorant”.

- The carton images should depict the actual carton label with the complete labeling information on the PDP rather than a stylized image.

- To complete the record under these supplements, submit the format specifications per 21 CFR 201.66(d) and 21 CFR 201.62(h).

Mucinex (600 mg guaifenesin) 48-Count Outer Container (Sample Tray) Label:

- To complete the record under these supplements, submit the format specifications per 21 CFR 201.66(d) and 21 CFR 201.62(h).

Mucinex (600 mg guaifenesin) Immediate Container (2-count sample pouch) Label:

- We recommend that the minimum text size be at least 6 pt.

NDA 21620/S-43

Mucinex-DM (600 mg guaifenesin, 30 mg dextromethorphan HBr) 2-Count Outer Container (Retail Sample Carton) Label:

- To complete the record under these supplements, submit the format specifications per 21 CFR 201.66(d) and 21 CFR 201.62(h).

We remind you that labeling changes, with certain exceptions noted in 21 CFR 314.70(d), must be submitted for FDA review and approval. In addition, we remind you to submit clean proposed labeling (without proprietary information), and labels annotated with the format specifications per 21 CFR 201.66(d) and 21 CFR 201.62(h).

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must include the labeling listed in the tables below, with the agreed upon revisions, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

We remind you to ensure that the carton labeling on the product website is consistent with the FPL.

Table 1. NDA 21282: Mucinex (guaifenesin 600 mg) and Maximum Strength Mucinex (guaifenesin 1200 mg) extended-release tablet

Drug Products	Submitted Draft Labeling	Date Submitted
Mucinex (guaifenesin 600 mg) extended-release tablet	6-count blister card	8/21/2020
	12-count blister card	8/21/2020
	17-count blister card	8/21/2020
	20-count blister card	8/21/2020
	6-count carton (1 x 6-count blister)	2/1/2021
	20-count carton (1 x 20-count blister)	2/1/2021
	24-count carton (2 x 12-count blister)	2/1/2021

Drug Products	Submitted Draft Labeling	Date Submitted
	40-count carton (2 x 20-count blister)	2/1/2021
	68-count carton (4 x 17-count blister)	2/1/2021
	80-count carton (40-count + 40-count bundle)	2/1/2021
	100-count carton (5 x 20-count blister)	2/1/2021
	120-count carton (100-count + 20-count bundle)	2/1/2021
	500-count bottle	2/1/2021
	2-count immediate container (HCP sample pouch)	8/21/2020
	20-count outer container – pouch carton and folder (10 x 2-count pouch)	8/21/2020
	48-count outer container – sample bin (24 x 2-count pouch)	8/21/2020
Maximum Strength Mucinex (guaifenesin 1200 mg) extended-release tablet	7-count blister card	8/21/2020
	9-count blister card	8/21/2020
	12-count blister card	8/21/2020
	14-count blister card	8/21/2020
	7-count carton (1 x 7-count blister)	2/1/2021
	14-count carton (1 x 14-count blister	2/1/2021
	18-count carton (2 x 9-count blister)	2/1/2021
	28-count carton (2 x 14-count blister)	2/1/2021
	42-count carton (3 x 14-count blister)	2/1/2021
	48-count carton (4 x 12-count blister)	2/1/2021

**Table 2. NDA 21620: Mucinex-DM (guaifenesin 600 mg and dextromethorphan HBr 30 mg) and
Maximum Strength Mucinex-DM (guaifenesin 1200 mg and dextromethorphan HBr 60 mg) extended-release tablet**

Drug Products	Submitted Draft Labeling	Date Submitted
Mucinex-DM (guaifenesin 600 mg and dextromethorphan HBr 30 mg) extended-release tablet	6-count blister card	8/21/2020
	12-count blister card	8/21/2020
	17-count blister card	8/21/2020
	20-count blister card	8/21/2020
	6-count carton (1 x 6-count blister)	2/1/2021
	20-count carton (1 x 20-count blister)	2/1/2021
	24-count carton (2 x 12-count blister)	2/1/2021
	40-count carton (2 x 20-count blister)	2/1/2021
	68-count carton (4 x 17-count blister)	2/1/2021
	2-count immediate container (HCP sample pouch)	8/21/2020
	2-count immediate container (retail pouch)	8/21/2020
	2-count carton (2-count retail pouch)	8/21/2020
	48-count outer container – HCP sample tray (24 x 2-count HCP sample pouch)	8/21/2020
Maximum Strength Mucinex-DM (guaifenesin 1200 mg and dextromethorphan HBr 60 mg) extended-release tablet	7-count blister card	8/21/2020
	9-count blister card	8/21/2020
	12-count blister card	8/21/2020
	14-count blister card	8/21/2020

Drug Products	Submitted Draft Labeling	Date Submitted
	7-count carton (1 x 7-count blister)	2/1/2021
	14-count carton (1 x 14-count blister	2/1/2021
	18-count carton (2 x 9-count blister)	2/1/2021
	28-count carton (2 x 14-count blister)	2/1/2021
	42-count carton (3 x 14-count blister)	2/1/2021
	48-count carton (4 x 12-count blister)	2/1/2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21282/S-54 and NDA 21620/S-43**, as appropriate**.** 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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, PharmD, Regulatory Project Manager, at 301-796-9618.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Deputy Director
Division of Nonprescription Drugs 1
Office of Nonprescription Drugs
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/

NUSHIN F TODD
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