NDA 021620/S-45

SUPPLEMENT APPROVAL

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

Dear Ebru Unver Kulak:

Please refer to your supplemental new drug application (sNDA) dated and received February 6, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex DM (guaifenesin 600 mg / dextromethorphan hydrobromide 30 mg) and Maximum Strength Mucinex DM (guaifenesin 1200 mg / dextromethorphan hydrobromide 60 mg) extended-release tablets.

This Prior Approval supplemental new drug application provides labeling updates for the following products:

- Mucinex DM:
  - 2-count retail sachet and 2-count HCP sample sachet
  - 6-count, 20-count, 40-count, and 80-count cartons
  - 48-count HCP sample tray
  - 6-count and 20-count blisters

- Maximum Strength Mucinex DM:
  - 7-count, 14-count, 28-count, 42-count, and 56-count cartons
  - 7-count and 14 count blisters

This supplement also includes labeling revisions from the supplement approved February 19, 2021, under NDA 021620/S-43.

APPROVAL & LABELING

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

We note that you have committed in your email dated August 6, 2024, that you intend to make the agreed-upon revisions below:

- Bold the statement of identity (SOI) on all labeling, as required by 21 CFR 201.61(c).

- On the 2-count sachet (retail and healthcare provider (HCP) sample), move the net quantity statement, “2 Extended-Release Tablets” such that it be included in the SOI and bolded. The draft guidance, Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products Draft Guidance for Industry, recommends that the dosage form be included in the SOI.

We also have a recommendation regarding the expiration date format.
As currently presented in the proposed Mucinex DM, 2-count pouch container label, “DATE/LOT CODE” appears as an expiration date placeholder, but it is unclear if “MMDDYY” is intended to be the expiration date format, which is not an FDA recommended expiration date format. As the expiration date format is not provided in the other container labels and carton labeling, we are unable to assess the proposed expiration date format from a medication error perspective. To minimize confusion and reduce the risk for deteriorated drug medication errors, FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. Therefore, on the Mucinex DM and Maximum Strength Mucinex DM container labels and carton labeling, FDA recommends that the expiration date appear in YYYY-MM-DD format, if only numerical characters are used, or in YYYY-MMM-DD format, if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, to be expressed as YYYY-MM if only numerical characters are used, or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or forward slash be used to separate the portions of the expiration date.

LABELING

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

Submitted Draft Labeling	Date submitted
Mucinex DM 2-count HCP sample sachet	5/17/2024
Mucinex DM 2-count retail sachet	5/17/2024
Mucinex DM 6-count carton	6/28/2024
Mucinex DM 6-count blister card	2/6/2024
Mucinex DM 20-count carton	6/28/2024
Mucinex DM 20-count blister card	2/6/2024
Mucinex DM 40-count carton	6/28/2024

Mucinex DM 48-count HCP sample tray	6/28/2024
Mucinex DM 80-count carton	6/28/2024
Maximum Strength Mucinex DM 7-count carton	6/28/2024
Maximum Strength Mucinex DM 7-count blister card	2/6/2024
Maximum Strength Mucinex DM 14-count carton	6/28/2024
Maximum Strength Mucinex DM 14-count blister card	2/6/2024
Maximum Strength Mucinex DM 28-count carton	6/28/2024
Maximum Strength Mucinex DM 42-count carton	6/28/2024
Maximum Strength Mucinex DM 56-count carton	6/28/2024

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 021620/S-045**." 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.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the

[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

supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Tam Dinh, PharmD, Regulatory Project Manager at (240) 402-6284, or email Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Blister 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
08/06/2024 04:04:23 PM