

NDA 021585/S-038

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 January 8, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex D (guaifenesin 600 mg/ pseudoephedrine HCl 60 mg) and Maximum Strength Mucinex D (guaifenesin 1200 mg/ pseudoephedrine HCl 120 mg) extended-release tablets.

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

- Mucinex D: 18- and 36-count carton and 18-count blister
- Maximum Strength Mucinex D: 24-count carton and 12-count blister

This supplement also includes labeling revisions from previously approved supplements under NDA 021282/S-54 and NDA 021620/S-43, dated February 19, 2021.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 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 D 18-count carton	6/28/2024
Mucinex D 36-count carton	6/28/2024

Mucinex D 18-count blister	1/8/2024
Maximum Strength Mucinex D 24-count carton	6/28/2024
Maximum Strength Mucinex D 12-count blister	1/8/2024

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 021585/S-038.**” 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 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).

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

Sincerely,

{See appended electronic signature page}

Martha Lenhart, MD, PhD
Deputy 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/

MARTHA K LENHART
07/08/2024 04:37:53 PM