NDA 217338

NDA APPROVAL

RB Health (US) LLC
Attention: Michael Cammarata
Director, Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Dear Michael Cammarata:

Please refer to your new drug application (NDA) dated and received September 29, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex 12HR Cold & Fever Multi-Symptom (naproxen sodium 110 mg, dextromethorphan hydrobromide 30 mg, guaifenesin 600 mg) extended-release tablet.

We acknowledge receipt of your amendment dated July 7, 2025, which constituted a complete response to our July 26, 2024, action letter.

This new drug application provides for the use of Mucinex 12HR Cold & Fever Multi-Symptom (naproxen sodium 110 mg, dextromethorphan hydrobromide 30 mg, guaifenesin 600 mg) extended-release tablets for the following:

- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- Temporarily relieves
  - Cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - The intensity of coughing
  - The impulse to cough to help you get to sleep
  - Minor aches and pains due to headache and the common cold
- Temporarily reduces fever

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 agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), 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 enclosed labeling, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date submitted
4-count carton healthcare provider sample	10/24/2025
8-count carton	10/24/2025
16-count carton	10/24/2025
32-count carton	10/24/2025
60-count carton	10/24/2025
4-count blister card	7/7/2025
8-count blister card	7/7/2025
10-count blister card	7/7/2025
4-count peel-back DFL	10/24/2025
8-, 16-, 32-, and 60-count peel-back DFL	10/24/2025

The final printed labeling 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 217338**." 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 & 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

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations; therefore, no additional pediatric studies are needed at this time.

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, contact Tam Dinh, PharmD, Regulatory Project Manager, at 240-402-6284 or 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 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/

YUNZHAO REN
12/22/2025 05:15:23 PM

NUSHIN F TODD
12/22/2025 05:15:56 PM