

NDA 021620/S-040

**APPROVAL LETTER** 

RB Health (US) LLC Attention: Punam Desai Regulatory Affairs Director 399 Interpace Parkway Parsippany, NJ 07054-0225

Dear Ms. Desai:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 2, 2019, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex® DM (guaifenesin and dextromethorphan HBr) extended release tablets, 600 mg / 30 mg and Maximum Strength Mucinex® DM (guaifenesin and dextromethorphan HBr) extended release tablets, 1200 mg / 60 mg.

This Prior Approval supplemental new drug application provides for the removal of and revisions to the approved stability protocol to remove

## **APPROVAL**

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

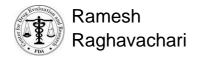
We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



Digitally signed by Ramesh Raghavachari

Date: 1/31/2020 09:49:31AM

GUID: 502d0913000029f375128b0de8c50020