NDA 021282/S-051

**APPROVAL LETTER**

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

Dear Ms. Desai:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 19, 2019, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mucinex® (600 mg guaifenesin) Extended-Release Bilayer Tablets and Maximum Strength Mucinex® (1200 mg guaifenesin) Extended-Release Bilayer Tablets.

This Prior Approval supplemental new drug application provides for changes to the approved stability protocol for the drug product.

**APPROVAL**

We have completed our review of this supplemental new drug application. 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

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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