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 (b) (4) and revisions to the approved stability protocol to remove (b) (4)

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

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
Date: 1/31/2020 09:49:31AM
GUID: 502d0913000029f375128b0de8c50020