NDA 018658/S-031

APPROVAL LETTER

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

Dear Ms. Desai:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 24, 2019, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym (dextromethorphan polistirex) Extended Release Suspension.

This Prior Approval supplemental new drug application provides for changes in the Release Rate method for the drug product and revised specifications to ensure that the drug product has the potency it purports to represent in 12 hours extended release.

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
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