NDA 018658/S-34

SUPPLEMENT APPROVAL

RB Health (US) LLC
Attention: Linda Salerno
Manager Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054-0225

Dear Linda Salerno:

Please refer to your supplemental new drug application (sNDA) dated and received October 17, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym (dextromethorphan polistirex) extended-release oral suspension, 30 mg per 5 mL.

We also refer to your September 15, 2023, resubmission which constituted a complete response to our April 17, 2023 action letter.

This “Prior Approval” supplemental new drug application provides for a change in the graphical layout for all carton and immediate container (bottle) labels and a change in nomenclature of an inactive ingredient.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below, submitted September 15, 2023.

Label Item	Description
0.5 fl oz carton, outer container 0.5 fl oz bottle, immediate container	Adult Grape
3 fl oz carton, outer container 3 fl oz bottle, immediate container	Adult Grape
3 fl oz carton, outer container 3 fl oz bottle, immediate container	Adult Orange
5 fl oz carton, outer container 5 fl oz bottle, immediate container	Adult Grape
5 fl oz carton, outer container 5 fl oz bottle, immediate container	Adult Orange
2 x 5 fl oz carton, outer container	Adult Grape
2 x 5 fl oz carton, outer container	Adult Orange
3 fl oz carton, outer container 3 fl oz bottle, immediate container	Children's Grape
3 fl oz carton, outer container 3 fl oz bottle, immediate container	Children's Orange
5 fl oz carton, outer container 5 fl oz bottle, immediate container	Children's Grape

The FPL 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 018658/S-34**." 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 and 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.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

[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

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 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 Drug
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/

NUSHIN F TODD
03/15/2024 09:57:45 AM