DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018658/S-030

SUPPLEMENT APPROVAL

Reckitt Benckiser LLC
Attention: Donna Alvarez
Regulatory Operations Lead, Health
399 Interpace Parkway,
Parsippany, NJ 07054

Dear Ms. Alvarez:

Please refer to your Supplemental New Drug Application (sNDA) dated December 20, 2013, received December 23, 2013 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym® (dextromethorphan polistirex) extended-release suspension, equivalent to dextromethorphan hydrobromide 30 mg per 5 mL.

We also refer to our approval letter dated June 19, 2014 which contained the following error: The labeling images in the attached labeling were incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 19, 2014, the date of the original approval letter.

We acknowledge receipt of your amendments dated March 6 and May 29, 2014.

This "Prior Approval" sNDA provides for a revision of the proprietary name layout and updated graphics for the pediatric labeling of the orange and grape-flavored SKUs.

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 agreed-upon labeling text.

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 enclosed labeling submitted March 6, 2014 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. FPL must be submitted for all representative count sizes (i.e., representative labeling is not acceptable in the FPL submission).

Delsym® (dextromethorphan polistirex) extended-release suspension

- Children's Outer Carton 5 fl oz grape flavor

- representative of the Children's Outer Carton 3 fl oz grape flavor
- Children's Immediate Container (bottle) 5 fl oz grape flavor
  - representative of the Children's Immediate Container (bottle) 3 fl oz grape flavor
- Children's Outer Carton 5 fl oz orange flavor
  - representative of the Children's Outer Carton 3 fl oz orange flavor
- Children's Immediate Container (bottle) 5 fl oz orange flavor
  - representative of the Children's Immediate Container (bottle) 3 fl oz orange flavor

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018658/S-030**." 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. 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.

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 any questions, call Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
06/19/2014