DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018658/S-029

SUPPLEMENT APPROVAL

Reckitt Benckiser, Inc.
Attention: Barbara Spallitta
Director, Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Dear Ms. Spallitta:

Please refer to your Supplemental New Drug Application (sNDA) dated November 15, 2010 received November 16, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym® (dextromethorphan polistirex) extended-release oral suspension, 30 mg/5 mL.

We acknowledge receipt of your amendments dated November 15 and 22, December 7 and 22, 2010, April 20 and 29, 2011.

This "Prior Approval" sNDA provides for change in the graphical layout for both the 3 fl. oz- and 5 fl. oz "adult" and "pediatric" orange and grape flavored carton and immediate container labels. In addition, this sNDA provides for the replacement of the term "vegetable oil" with "partially hydrogenated soybean oil" on the list of inactive ingredients found on the Drug Facts label.

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, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling listed below:

1. 5 fl oz carton and immediate container (bottle) labels (adult graphic, orange-flavored) submitted on April 20, 2011[representative of the 3 fl oz carton and immediate container (bottle) labels (adult graphic, orange-flavored)];

2. 5 fl oz carton and immediate container (bottle) labels (adult, grape-flavored) submitted on April 20, 2011 [representative of the 3 fl oz carton and immediate container (bottle) labels (adult, grape-flavored)];

3. 3 fl oz carton label (pediatric, orange-flavored) submitted on December 22, 2010 [representative of the 5 fl oz carton label (pediatric, orange-flavored)];

4. 3 fl oz carton label (pediatric, grape-flavored) submitted on December 22, 2010 [representative of the 5 fl oz carton label (pediatric, grape-flavored)];

5. 3 fl oz immediate container (bottle) label (pediatric, orange-flavored) submitted on November 15, 2010 [representative of the 5 fl oz immediate container (bottle) label (pediatric, orange-flavored)];

6. 3 fl oz immediate container (bottle) label (pediatric, grape-flavored) submitted on November 15, 2010 [representative of the 5 fl oz immediate container (bottle) label (pediatric, grape-flavored)].

The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling 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-029**." Approval of this submission by FDA is not required before the labeling is used. Please note that representative labeling is not acceptable for FPL submissions and that FPL should be submitted in the final to be marketed format.

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Janice Adams-King
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building #22, Room: 5408
10903 New Hampshire Avenue
Silver Spring, Maryland **20993**

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Janice Adams-King
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building #22, Room: 5408
10903 New Hampshire Avenue
Silver Spring, Maryland **20903**

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Immediate 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/

ANDREA LEONARD SEGAL
05/16/2011