DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018658/S-028

SUPPLEMENT APPROVAL

Reckitt Benckiser, Inc.
Attention: Douglas Flint
Manager, Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Flint:

Please refer to your Supplemental New Drug Application (sNDA) dated May 12, 2010, received May 13, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym® (dextromethorphan hydrobromide) extended-release oral suspension, 30 mg/5mL.

This "Changes Being Effected" supplemental new drug application provides for alternate oval-shaped immediate containers for the 3- and 5-fluid ounce packaging sizes.

Your May 12, 2010 correspondence notified us that the labels for the 5-fluid ounce grape and orange-flavored (pediatric) cartons and immediate containers are representative of the labels for the 3-fluid ounce grape and orange-flavored (pediatric) cartons and immediate containers. Also, the labels for the 3-fluid ounce (adult graphic) grape and orange-flavors cartons and immediate containers are representative of the labels for the 5-fluid ounce grape and orange-flavored (adult graphic) cartons and immediate containers. Any changes approved for this representative labeling will be incorporated into the labeling of the other package sizes, which are identical with the exception of the volume.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 submitted on May 12, 2010 (labels for the adult 3-fluid ounce orange-flavored and grape-flavored cartons and immediate containers, and the labels for the pediatric 5-fluid ounce orange-flavored and grape-flavored cartons and immediate containers), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

FPL must be submitted for all of the referenced volumes. Representative labeling will not be acceptable in the FPL submission.

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-028**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

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 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
11/10/2010