DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018658/S-027 **SUPPLEMENT APPROVAL**

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

Dear Ms. Spallitta:

Please refer to your October 7, 2009 Supplemental New Drug Application (sNDA), received October 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Delsym® Extended-Release Oral Suspension, dextromethorphan polistirex (equivalent to 30 mg dextromethorphan HBr/5 mL).

We acknowledge receipt of your correspondences dated November 10, 2009 and April 2, 2010.

Your April 2, 2010 correspondence notified us that the 3 fl oz (pediatric graphic) grape and orange-flavors is also representative of the 5 fl oz (pediatric graphic) grape and orange-flavors, and the 5 fl oz (adult graphic) grape and orange-flavors is also representative of 3 fl oz (adult graphic) grape and orange-flavors. The above referenced correspondence indicated that these intended to serve as representative package sizes. 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 count size.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

1. The addition of a "See New Dosing Directions" flag to the PDP
2. The addition of the statement "Do not use dosing cup with other products" following the statement "Measure only with dosing cup provided" under the Directions heading of the Drug Facts panel and the dosing chart on the side panel of the outer carton.
3. The revision of the term "Dosage cup" to "Dosing cup" to the carton and immediate container labels

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.

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 (carton and immediate container (bottle) labels for the 3 fl. oz. (89 ml) grape and orange flavor adult and pediatric SKUs, carton and immediate container (bottle) labels for the 5 fl. oz. (148 ml) grape flavor adult and pediatric SKUs, and the 15 ml (physician sampling) grape and orange flavor carton (sample tray) and immediate container (bottle) labels submitted on October 7, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

FPL must be submitted for all of the referenced count sizes. 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 (October 2005).* 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-027**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "See New Dosing Directions" from the principal display panel after six months of marketing.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18658	SUPPL-27	RECKITT BENCKISER	DELSYM

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

/s/

JOEL SCHIFFENBAUER
04/08/2010