



NDA 18-658/S-026

SUPPLEMENT APPROVAL

Reckitt Benckiser, Inc.
Attention: Barbara Spallitta
Regulatory Affairs North America – Healthcare
399 Interpace Parkway
Parsippany, NJ 07054-0225

Dear Ms. Spallitta:

Please refer to your supplemental new drug application dated April 6, 2009, received April 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delsym[®] Extended-Release Suspension, dextromethorphan polistirex (equivalent to 30 mg dextromethorphan HBr/5 ml).

We acknowledge receipt of your submission dated August 4, 2009.

This Changes Being Effected supplemental new drug application proposes to revise the dosing instructions to incorporate the currently approved adult and child dosing down to 4 years of age on all SKUs and the addition of a new dosage cup.

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 and with the minor editorial revisions listed below/indicated in the enclosed labeling.

1. Add the “Dosage Cup Included” flag to the 5 fl oz grape flavor “adult” and “pediatric” SKU carton and container labels, and to the 15 ml grape and orange flavor sample container labels at the time of next printing or within 180 days, whichever comes sooner.

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 container labels for the 5 fl oz (148 ml) grape flavor adult and pediatric SKUs submitted on April 6, 2009; and the carton and container labels for the 3 fl oz (89 ml) grape and orange flavor adult and pediatric SKUs, the 5 fl oz (148 ml) orange flavor adult and pediatric SKUs, and the 15 ml grape and orange flavor sample tray and container labels (physician sampling) submitted on August 4, 2009. Labeling 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 (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 18-658/S-026.**” Approval of this submission by FDA is not required before the labeling is used.

Per your August 4, 2009 letter of commitment, we remind you of your agreement to make the following labeling revisions at the time of next printing:

1. Revise the Drug Facts Panel under the subheading “Directions” to include the bulleted statement “Measure only with dosage cup provided” at the time of next printing or within 180 days, whichever comes sooner.

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 Michelle Poindexter, Regulatory Project Manager, at (301) 796-4795.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18658	SUPPL-26	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/

ANDREA LEONARD SEGAL
10/08/2009