DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-658/S-023

Reckitt Benckiser
Attention: Barbara Spallitta
Director, Regulatory Affairs
399 Interpace Parkway
P.O. Box 225
Parisippany, NJ 07054

Dear Ms. Spallitta:

Please refer to your supplemental new drug application dated June 4, 2008, received June 6, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Delsym® (dextromethorphan polistirex) Extended-Release Suspension, 30 mg/5 mL.

We acknowledge receipt of your submissions dated October 6, 2008 and December 3, 2008.

This supplemental new drug application provides the following changes associated with the Drug Facts labeling for Delsym® Extended-release Suspension, 30 mg/5 mL for the 5 fl oz carton and container labels:

- Directions were revised from "Children under 2 years of age: consult a doctor" to "Children under 4 years of age: do not use" in accordance with the voluntary action taken by CHPA member companies to address concerns about safety and efficacy of oral OTC pediatric cough and cold medications.
- The sodium content was revised from 6 mg to 5 mg.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text. Only the labels for the referenced package size are approved for use under this application.

The FPL must be identical to the enclosed labeling (5 fl oz carton and container labels submitted on October 7, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 18-658/S-023**." Approval of these submissions by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We remind you that the "See New Directions" flag must be removed from the labeling wherever it appears after 180 days of marketing. This revision can be reported in the next annual report.

Additionally, as described in your letter of commitment to the Agency dated December 3, 2008, you will test three lots of Delsym® Extended-Release Suspension in triplicate and will provide the test results to the Agency by January 2, 2009. You should be aware that the sodium content labeling may need to change if the data do not support your revised sodium content of 5 mg.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

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.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

/s/

Andrea Segal

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