DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 18-658/S-014

Medeva Americas, Inc.
Attention: Cheryl Rini, R.N.
Senior Manager, Regulatory Affairs
755 Jefferson Road
P.O. Box 1710
Rochester, NY 14603-1710

Dear Ms. Rini:

Please refer to your supplemental new drug application dated March 31, 1999, received April 7, 1999, 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 submission of final printed labeling (FPL) dated June 29, 1999.

This "Changes Being Effected" supplemental new drug application provides for changes to the approved labeling for the drug product as follows:

- removal of "nonalcoholic" from the immediate container label and carton;
- the amount of alcohol (0.26%) will be stated on the labeling in accordance with 21 CFR 328.50; and
- "alcohol 0.26%" has been added to the list of inactive ingredients on the carton labeling.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted on June 29, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Please revise the labeling for this drug product in accordance with the provisions of the March 17, 1999 FEDERAL REGISTER document "Over-the-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254) which has been incorporated into the regulations of 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule. You may submit this revised labeling as a "Changes Being Effected" supplemental new drug application or as a change that may be described in your next annual report to this application.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this application, please call Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research