DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-128/S-009

McNeil Consumer Healthcare
Attention: John Hauser
Associate Director Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Mr. Hauser:

Please refer to your supplemental new drug application dated October 28, 2008, received October 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin® Cold (100 mg/5 ml ibuprofen and 15 mg/5 ml pseudoephedrine HCl) suspension.

We acknowledge receipt of your submission dated April 22, 2009.

This "Changes Being Effected" supplemental new drug application provides the revised cardiovascular warning statement bulleted under the "*Warnings*" subheading, "When using this product, the risk of heart attack or stroke may increase if you use more than directed or for longer than directed" and the addition of the warning statement "Ask a doctor before use if the child has asthma" to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letters .

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text for the 4 oz. carton and bottle (berry flavor).

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 labels (4 oz. bottle label (berry flavor), submitted October 28, 2008 and 4 oz. carton (berry flavor), submitted April 22, 2009), and 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 21-128/S-009**." Approval of this submission by FDA is not required before the labeling is used.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, email or call Michelle Poindexter, Regulatory Project Manager, at michelle.poindexter@fda.hhs.gov or (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

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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