DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-128/S-007

McNeil Consumer & Specialty Pharmaceuticals
Attention: Hina S. Harlow, Pharm.D.
Manager, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated August 11, 2005, received August 12, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin Cold (100 mg/5 mL ibuprofen and 15mg/5 mL pseudoephedrine HCl) suspension.

We also acknowledge receipt of your submission dated November 4, 2005.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the Children's Motrin Cold 4 oz package size in response to the June 14 and July 15, 2005 supplement request letters.

We have completed our review of this application, as amended. This application is approved for the 4 oz package size, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (Dye Free Berry, Berry, and Grape-flavored 4 oz immediate container and carton labels submitted November 4, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units** 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 this submission "**FPL for approved supplement NDA 21-128/S-007**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreement, per telephone conversation on December 8, 2005 with Hina Wu, to make the following revision to the Drug Facts label at the time of next printing:

> Under ***Active Ingredients***, relocate the footnote statement "*nonsteroidal anti-inflammatory drug" to below the line identifying "Pseudoephedrine HCl 15 mg" as a nasal decongestant.

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, HFD-410
FDA
5600 Fishers Lane
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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Acting 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

12/21/2005 08:36:52 AM