DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-516/S-018

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

Dear Dr. Wu:

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 (100 mg/5 mL ibuprofen) 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 4 oz, 2 oz, and 1 oz package sizes 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, 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, Berry (hospital use), Tropical Punch, Grape, and Bubblegum- flavored 4 oz, Berry- flavored 2 oz, and Berry, Grape, Bubblegum- flavored 1 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 20-516/S-018**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitment, stated in your submission dated November 4, 2005, to make the following revision to the Drug Facts label at the time of next printing:

> Under the warning "**Keep out of reach of children**", relocate the toll-free number for Poison Control Center after the required text (see 21 CFR 330.1(g)) to read **"Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)".

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

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