DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-601/S-013

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 December 8, 2005, received December 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin (50 mg ibuprofen) chewable tablets and Motrin Junior Strength (100 mg ibuprofen) chewable tablets.

We also acknowledge receipt of your submission dated January 17, 2006.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the Motrin Junior Strength 24-count package size in response to the June 14, and July 15, 2005 supplemental labeling request letters.

We have completed our review of this application. This application is approved for the Motrin Junior Strength 24-count 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 (Orange and Grape-flavored 24-count carton and immediate container labels submitted December 8, 2005), 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 this submission "**FPL for approved supplement NDA 20-601/S-013**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of the following commitments listed below:

1. In your submission dated January 17, 2006, you agree to make the following revisions to the labeling for Motrin Junior Strength at the time of next printing in March 2006:

a. *Principal Display Panel*

Move the word "(NSAID)" from its current location to immediately follow the name of the NSAID ingredient "Ibuprofen Tablets".

b. *Drug Facts Panel (Carton)*

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)".

2. According to your January 17, 2006 submission, Children's Motrin is being discontinued. Should you decide to re-introduce Children's Motrin in the future, you agree to submit revised labeling in response to the June 14, and July 15, 2005 supplemental labeling request letters at that time.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, 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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