



NDA 20-601/S-014

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 March 2, 2006, received March 3, 2006, 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.

This supplemental new drug application provides for the addition of dosing directions for children 2 to 5 years of age to the Drug Facts label for Junior Strength Motrin.

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 labels submitted March 2, 2006), 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-014**". Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the statement "New! Expanded Dosing for Ages 2- 11" from the Principal Display Panel 6 months after introduction into the market place.

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

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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
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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