DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020516/S-022

SUPPLEMENT APPROVAL

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

Dear Mr. Hauser:

Please refer to your Supplemental New Drug Application (sNDA) dated April 22, 2010, received April 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Motrin (ibuprofen) oral suspension, 100 mg/5 mL.

We acknowledge receipt of your amendment dated July 15, 2010.

This "Changes Being Effected" supplemental new drug application provides for the addition of the organ-specific warnings specified in the Organ-Specific Warnings final rule (74 FR 19385) and the removal of the statement "do not take longer than 10 days, unless directed by a doctor (see new warnings)" per the FDA's General Advice letter dated September 4, 2009.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

- Under Warnings, under the heading, "Stop use and ask a doctor if," add an "s" to the word "experience" so that the bulleted statement correctly reads: "[bullet] child experiences any of the following signs of stomach bleeding."

Submit final printed labeling, with the revision listed above, 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 labeling with the incorporated minor editorial change (bubblegum and berry flavored 30 mL (1 fl oz) immediate container (bottle) and carton labels, berry flavored 60 mL (2 fl oz) immediate container (bottle) and carton labels , and bubblegum, berry, dye-free berry, and tropical punch flavored 120 mL (4 fl oz) immediate container (bottle) and carton labels submitted April 22, 2010), 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 (June 2008)." 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 020516/S-022**." Approval of this submission by FDA is not required before the labeling is used.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, , M.D.,
Deputy Division Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
10/19/2010