DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020603/S-014

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 September 18, 2009, received September 21, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Motrin Infants' Drops (50 mg/ 1.25 ml ibuprofen) oral suspension.

We acknowledge receipt of your amendment dated April 22, 2010.

The April 22, 2010, submission constituted a complete response to our March 19, 2010, action letter.

This "Changes Being Effected" supplemental new drug application provides for revised labeling in accordance with the April 29, 2009 final monograph for Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use. This supplemental NDA also provides for the removal of the directions statement "do not take longer than 10 days, unless directed by a doctor (see warnings)" in response to the September 04, 2009 general advice letter from FDA.

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.

LABELING

Submit final printed labeling 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 [Motrin Infants' Drops (Berry flavored ¼- and ½- fluid ounce), and (Dye-Free Berry flavored ½- and 1-fluid ounce) carton and immediate container (bottle) 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 (October 2005)". 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 020603/S-014**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20603	SUPPL-14	MCNEIL CONSUMER HEALTHCARE	INFANT'S MOTRIN

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
07/15/2010