DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-012/S-040

McNeil Consumer Healthcare
Attention: Hina S. Harlow, Pharm.D.
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated June 1, 2007, received June 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin IB (200 mg ibuprofen) tablets and Motrin Migraine Pain (200 mg ibuprofen) tablets.

We acknowledge receipt of your submissions dated June 12 and 19, and October 9, 2007.

This supplemental new drug application provides for the addition of the warning statement "Ask a doctor or pharmacist before use if you are [bullet] taking aspirin for heart attack or stroke because ibuprofen may decrease this benefit of aspirin" to the Drug Facts label for the Motrin IB 2-, 24-, 50-, 60-, 100-, 225-, 300-, and 500-count caplet package sizes, and 24-, 50- and 100-count tablet package sizes in response to the September 26, 2006, supplemental labeling request letter.

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 final printed labeling (FPL) for the Motrin IB, 24-, 50-, 60-, 100-, 300- and 500-count caplet and 24-, 50-, and 100-count tablet immediate container and carton labels, 225-count caplet immediate container label, and 2-count caplet pouch submitted October 9, 2007.

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 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}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

Enclosure

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

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