DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-012/S-038

McNeil Consumer Healthcare
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 July 7, 2006 received June 8, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin IB (200 mg ibuprofen) tablets.

We acknowledge receipt of your submission dated August 14, 2006.

This supplemental new drug application provides for the addition of a non-child resistant (NCR) bottle package for Motrin IB caplets. The proposed 175-cc NCR bottle package would replace the currently marketed 75-cc NCR bottle package.

We have completed our review of this application. This application is approved for the 175-cc NCR bottle package of Motrin IB containing 225 caplets, 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 (Motrin IB 225-count caplet immediate container label submitted August 14, 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 19-012/S-038**". Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag “New!” from the principal display panel six months after introduction into the marketplace.

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}

Joel Schiffenbauer, MD
Deputy 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/

Joel Schiffenbauer

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