DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-012/S-037

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 August 11, 2005, received August 12, 2005, 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 also acknowledge receipt of your submissions dated December 15, 2005 and January 9, 2006.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the Motrin IB 165-, 100-, 100+25-, 50-, 50+15-, and 24-count tablet package sizes and 500-, 300-, 250-, 165-, 165+35-, 100-, 100+25-, 60-, 50-, 50+15-, 24-, 8-, and 2-count caplet package sizes in response to the June 14 and July 15, 2005 supplemental labeling request letters.

We have completed our review of this application. This application is approved for the Motrin IB 165-, 100-, 100+25-, 50-, 50+15-, and 24-count tablet package sizes and 500-, 300-, 250-, 165-, 165+35-, 100-, 100+25-, 60-, 50-, 50+15-, 24-, 8-, and 2-count caplet package sizes, 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 165-, 100-, 100+25-, 50-, 50+15-, and 24-count tablet and 500-, 300-, 250-, 165-, 165+35-, 100-, 100+25-, 60-, 50-, 50+15-, and 24-count caplet carton and immediate container labels, 8-count caplet blister card, and 2-count caplet pouch submitted December 15, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units** 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-037**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of the following commitments listed below:

1. In your submission dated December 15, 2005, you agree to make the following revision to the Drug Facts label at the time of next printing:

   Under the warning "**Keep out of reach of children**", relocate the toll-free number for Poison Control Center after the required text (see 21 CFR 330.1(g)) to read **"Keep out of reach of children**. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)".

2. According to your January 9, 2006 submission, Motrin Migraine Pain has been discontinued. You agree to submit revised labeling in response to the June 14 and July 15, 2005 supplemental labeling request letters prior to marketing Motrin Migraine Pain.

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}

Andrea Leonard-Segal, MD
Acting 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

2/8/2006 12:47:49 PM