DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019012/S-046

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.
Attention: John Hauser
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

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 Motrin IB (ibuprofen) tablets, 200 mg.

We acknowledge receipt of your amendments dated June 9, 2010, September 15, 2010, and October 7, 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.

1) Left-justify the "Stomach bleeding warning" subheading for the following carton labels:
Motrin IB Tablets
- 24-count carton label
- 50-count carton label
- 50+25-count carton label

Motrin IB Capsule-Shaped Tablet (Caplet)
- 24-count carton label
- 24+6-count carton label
- 50-count carton label
- 60-count carton label

2) Enhance the highlighting of the word "(NSAID)" on the Principal Display Panel (PDP) of the 500-count capsule-shaped tablet (caplet) immediate container label.

These changes should be made within 90 days of the date of this letter. Submit final printed labeling, with the revisions 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 changes, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted on April 22, 2010:
Motrin IB Tablets:

- Immediate Container Labels
  - 24-count immediate container label
  - 50-count immediate container label
  - 75-count immediate container label
  - 100-count immediate container label
  - 125-count immediate container label
  - 150-count immediate container label
- Carton Labels
  - 100-count carton label
  - 100+25-count carton label
  - 100+50-count carton label

Motrin IB Capsule-Shaped Tablet (Caplets):

- Immediate Container Labels:
  - 2-count immediate container label
  - 24-count immediate container label
  - 24+6-count immediate container label
  - 50-count immediate container label
  - 60-count immediate container label
  - 75-count immediate container label
- Carton Labels
  - 50+25-count carton label
  - 100+25-count carton label
  - 50x2-count carton label

Submitted on June 9, 2010:
Motrin IB Capsule-Shaped Tablet (Caplets):

- Immediate Container Labels:
  - 100-count immediate container label
  - 125-count immediate container label
  - 165-count immediate container label
  - 225-count immediate container label
  - 300-count immediate container label
- Carton Labels
  - 100-count carton label
  - 165-count carton label
  - 300-count carton label
  - 500-count carton label

Submitted on October 7, 2010
Motrin IB Tablets:

- Carton Labels
  - 24-count carton label
  - 50-count carton label
  - 50+25-count carton label

Motrin IB Capsule-Shaped Tablet (Caplets):

- Immediate Container Labels:
  - 500-count immediate container label
- Carton Labels
  - 24-count carton label
  - 24+6-count carton label
  - 50-count carton label
  - 60-count carton label

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 019012/S-046**." 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

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

Enclosures: 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
10/21/2010