DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-463/S-104

McNeil Consumer & Specialty Pharmaceuticals
7050 Camp Hill Road
Fort Washington, PA 19034

Attention: Hina S. Harlow, Pharm D
Manager, Regulatory Affairs

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated October 26, 2005, received October 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin (ibuprofen tablets, USP, 400 mg, 600 mg, 800 mg).

This supplemental new drug application was submitted in response to the Agency's letter dated June 14, 2005, requiring class labeling language for all non-selective non-steroidal anti-inflammatory drugs (NSAIDS), to include a boxed warning to address possible cardiovascular risks as well as known gastrointestinal risks, revised **CONTRAINDICATIONS, WARNINGS** and **PRECAUTIONS** sections of the package insert, and a **MedGuide** for NSAIDS.

We have completed our review of this application and it is approved, 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, and include the revisions agreed upon during a January 4, 2006 teleconference, to the enclosed labeling text for the package insert and the MedGuide. These revisions are terms of the approval of this application.

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 17-463/S-104**." Approval of this submission by FDA is not required before the labeling is used.

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 Jane Dean, Regulatory Project Manager, at (301) 796-1202.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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