NDA 19482/S-013
NDA 20135/S-005
NDA 20418/S-003
NDA 20476/S-002

McNeil Consumer Products
Attention: Vivian Chester
Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Chester:

Please refer to your supplemental new drug applications dated March 23, 1998, received March 24, 1998, for NDA 19-842/S-013, Motrin Suspension and October 6, 1998, received October 7, 1998 for NDA 20-135/S-005, Motrin Chewable Tablets 50 mg and 100 mg; NDA 20-418/S-003, Motrin Caplets 100 mg; NDA 20-476/S-002, Motrin Oral Drops 40 mg/ 5mL submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act .

We acknowledge receipt of your submissions dated October 7, 1998.

These supplemental new drug applications provide for multiple labeling changes.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 23, and October 6, 1998 and as amended on October 7, 1998).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19482/S-013, 20135/S-005, 20418/S-003, 20476/S-002." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Ms. Jane Dean Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
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/

Lee Simon
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