CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-012/S-016

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-012/S-016

McNeil Consumer Healthcare
Attention: Vivian Chester
Vice President, Regulatory Affairs and Project Management
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Chester:

Please refer to your supplemental new drug application dated February 26, 1999, received February 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin Migraine Pain (ibuprofen, 200 mg) tablets, caplets, and geltabs.

We acknowledge receipt of your communications dated March 20, April 16, July 28, October 22, and December 9, 1999, and January 14, 17, 19, and February 4, 18, 21, 23, 24(2), and 25, 2000.

This supplemental new drug application provides for the use of Motrin Migraine Pain (ibuprofen, 200 mg) tablets, caplets, and geltabs for treatment of pain of migraine headache.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text, and must be formatted consistent with the requirements of 21 CFR 201.66.

Please submit 20 copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FPL for approved supplement NDA 19-012/S-016." Approval of this submission by FDA is not required before the labeling is used.

You are reminded that the flag statement, "New," should be deleted after 6 months of marketing the product.

Should additional information relating to the safety of the drug become available, revision of that labeling may be required.

Please be advised that the agency has concerns about labeling changes for OTC drug products used to treat migraine or treat pain of migraine. These changes include, but are not limited to, (1) Changes in the product trade name, (2) Changes in the appearance of the product trade name (e.g. size, color, case), or (3) Promotional indications on the principal display panel. For this product, we do not consider any of these types of changes to be a minor or editorial change that can be made without agency pre-approval.

Be also advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit four copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Over-the-Counter Drug Products, one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
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 Practitioner" 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 regarding this application, please contact Kerry Rothschild, Esq., Regulatory Project Manager, at 301-827-2284.

Sincerely,

/S/

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/S/

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure