DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-402/S-005

MAR 16 2000

Whitehall-Robins Healthcare
Attention: Sharon Heddish
Vice President, Regulatory Affairs Worldwide
5 Giralda Farms
Madison, NJ 07940-0871

Dear Ms. Heddish:

Please refer to your supplemental new drug application dated May 14, 1999, received May 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Migraine Liqui-Gels (solubilized ibuprofen), 200 mg.

We acknowledge receipt of your communications dated September 8, November 19 and 23, and December 14, 1999; January 21 and 24, February 15 and March 9, and 14, 2000.

This supplemental new drug application provides for the use of Advil Migraine Liqui-Gels (solubilized ibuprofen), 200 mg for treatment of migraine.

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 enclosed agreed upon labeling text. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling text, and must be formatted consistent with the requirements of 21 CFR 201.66. Please be advised that, under the "Inactive ingredients" heading, you may replace the listing of the ink components (black iron oxide, lechitin, pharmaceutical glaze and simethicone) with the term "pharmaceutical ink."

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 20-402/S-005." Approval of this submission by FDA is not required before the labeling is used.

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

Be 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 one copy 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. For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to approved supplement 20-402/S-005.

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/

/S/

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

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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Enclosure