CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-944

APPROVAL LETTER

NDA 20-944

DEC 18 1998

Whitehall-Robins Healthcare
Attention: Hulon McCain
5 Giralda Farms
Madison, New Jersey 07940-0871

Dear Mr. McCain:

Please refer to your new drug application (NDA) dated December 19, 1997, received December 22, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Chewable Tablets (ibuprofen tablets), 50 mg and 100 mg.

We acknowledge receipt of your submissions dated February 12 and 23, March 20, April 17, July 16, October 5, November 10 and 20, and December 18, 1998.

This new drug application provides for the use of Advil Chewable Tablets (ibuprofen tablets), 50 mg and 100 mg for temporary reduction of fever and relief of minor aches and pains due to common cold, flu, sore throat, headaches and toothaches.

We have completed the review of this 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 labeling text. In your letter dated December 18, 1998, you agreed to the enclosed labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 20-944." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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 Anti-Inflammatory, Analgesic and Ophthalmic 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

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.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Kerry Rothschild, Project Manager, at (301) 827-2222.

Sincerely,

/S/ 12-18-98

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

/S/ 12-15-98

John E. Hyde, Ph.D. M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
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Center for Drug Evaluation and Research

Enclosure