CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20812

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-812

JAN 30 1998

Whitehall-Robins Healthcare
Attention: Sharon Heddish
5 Giralda Farms
Madison, New Jersey 07940-0871

Dear Ms. Heddish:

Please refer to your new drug application dated December 12, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediatric Advil Drops (ibuprofen suspension) 100 mg/2.5 mL. We also refer to our approvable letter of June 6, 1997.

We acknowledge receipt of your submissions dated June 10, July 11, 17, and 30, September 11, October 7 and 23, and November 21, 1997. The User Fee goal date for this application is January 31, 1998.

This new drug application provides for the temporary reduction of fever and the temporary relief of minor aches and pains due to colds, flu, sore throat, headaches and toothaches.

We have completed the review of this application, including the submitted draft labeling, 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 draft labeling in the submission dated July 30, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on July 30, 1997. Marketing the product with FPL that is not identical to this draft labeling 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 "FINAL PRINTED LABELING" for approved NDA 20-812. 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, revision of that labeling may be required.

In addition, please submit four copies of the introductory promotional material and also submit any planned package insert that you propose to use for this product. All proposed materials

should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550 , one copy to the Division of OTC Drug Products, HFD-560, and two copies of both the promotional material and the package insert directly to the Division of Drug Marketing, Advertising and Communications, HFD-40; all at the following address:

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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.

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, please contact Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely,

/s/ for 1/30/98

John E. Hyde, Ph.D., M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/s/ for 1/30/98

Debra L. Bowen, M.D.
Director
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-812
HFD-550/Div. files
HFD-002/ORM (with labeling)
HFD-105/Office Director
HFD-101/L.Carter
HFD-550/S.Cook
HFD-550/MO TL/Hyde
HFD-550/Pharm/Coulter/Chen
HFD-550/Chem/Ho/Patel
HFD-560/Mason/Neuner/Katz/Bowen
HFD-880/Biopharm/Lee/Bashaw
HFD-830/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFD-560/OTC (with labeling - for OTC Drug Products Only)
HFI-20/Press Office (with labeling)

Drafted by: Cook/January 22, 1998/nda20812.ap

APPROVAL

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Rockville MD 20857

NDA 20-812

Whitehall-Robins Healthcare
Attention: Sharon Heddish
5 Giralda Farms
Madison, NJ 07940-0871

Dear Ms. Heddish:

Please refer to your December 12, 1996, new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediatric Advil® Drops (ibuprofen suspension) 100 mg/2.5 mL.

We acknowledge receipt of your submissions dated January 6 and 23, February 3, March 4, and April 7, 1997.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit the following:

Redacted 1

page(s) of trade secret and/or confidential commercial information

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of the other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal or telephone conference to discuss what further steps need to be taken before the application may be approved.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely,

WAC 6/6/97

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

DLB

Debra L. Bowen, M.D.
Director
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Attachement: Labeling comments

cc:
NDA 20-812
HFD-550/Div. Files
HFD-560
HFD-105
HFD-002/ORM
HFD-92/DDM-DIAB
HFD-550/S.Cook
HFD-550/SPMS/LoBianco 6/6/97
HFD-550/MO/Widmark
HFD-550/MO TL/Hyde
HFD-550/Pharm/Coulter AWC 5/5/97
HFD-550/Chem/Ho
HFD-880/Biopharm/Lee SCL 5/5/97
HFD-101/L.Carter
DISTRICT OFFICE
HFD-40/DDMAC
HFD-560/Dir/Bowen DLB 6/6/97
HFD-560/PM/Mason

Drafted by: Cook/April 24, 1997/nda20812.ae
Revised: Chambers/Bowen 6/6/97

APPROVABLE (AE)