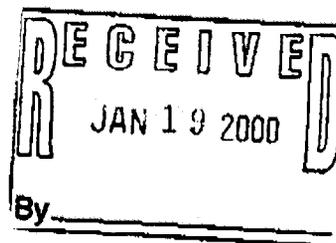


Food and Drug Administration
Rockville MD 20857

NDA 20-812/S-003

JAN 12 2000

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



Dear Ms. Heddish:

Please refer to your supplemental new drug application (supplemental NDA) dated June 15, 1998, received June 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infants' Advil (ibuprofen oral suspension) Concentrated Oral Drops, 50 mg/1.25 mL.

We acknowledge receipt of your submissions dated July 8, 1999, and January 5, 6, and 12 (two), 2000. Your submission of July 8, 1999 constituted a complete response to our April 15, 1999 action letter.

This supplemental NDA provides for the use of Infants' Advil (ibuprofen oral suspension) Concentrated Oral Drops, 50 mg/1.25 mL for ages 6 months to 23 months.

We have completed the review of this supplemental NDA, 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. We remind you, however, that the flag statement "New Infant Dosing" should be deleted after 6 months of marketing from initial approval.

The final printed labeling (FPL) for each representative package you intend to market must be identical to the enclosed labeling text, and must be formatted consistent with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text or format 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 supplement NDA 20-812/S-003." Approval of this submission by FDA is not required before the labeling is used.

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 note that you have fulfilled the pediatric study requirement at this time.

In addition, please submit three 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 submit one copy to this Division 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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

If you have any questions regarding this submission, please contact Kerry Rothschild, Esq., Regulatory Project Manager, at 301-827-2284.

Sincerely,

A handwritten signature in black ink, appearing to read 'S' followed by a flourish, is written over a horizontal line. To the right of the line, the initials 'MD' are written in a cursive style.

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

Enclosure