CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-128

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-128

AUG 1 - 2000

McNeil Consumer Healthcare
Attention: Jacqueline U. Linse
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

Dear Ms. Linse:

Please refer to your new drug application (NDA) dated September 30, 1999, received October 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Motrin Cold Suspension (ibuprofen/pseudoephedrine HCl suspension), 100 mg/5 mL and 15 mg/5 mL.

We acknowledge receipt of your submissions dated November 5 and 16; December 8, 1999; February 1, 4, and 11; April 27 (3); June 8, 16, 22, and 27; and July 7, 11, 17, and 28, 2000.

This new drug application provides for the use of Children's Motrin Cold Suspension (ibuprofen/pseudoephedrine HCl suspension) 100 mg/5 mL and 15 mg/5 mL for the temporary relief of nasal and sinus congestion, minor body aches and pains, fever, stuffy nose, headache, and sore throat.

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 agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter. Based on available stability data, an expiration period of 24 months is approved at this time. Future extension of the expiration period should be based on real time data.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) text and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit 20 paper 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved

NDA 21-128." 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 are waiving the pediatric study requirements for this action on this application for pediatric patients less than 2 years of age.

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 two 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 and one to the Division of Over-the-Counter Drug Products. For administrative purposes, this submission should be sent to the NDA and identified as a new correspondence to approved NDA 21-128.

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 Babette Merritt, Regulatory Project Manager, at (301) 827-2222.

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/

Karen Midthun, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure