CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-373

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-373

Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

Attention: David Smith, Ph.D.
Director, Regulatory Affairs

Dear Dr. Smith:

Please refer to your new drug application (NDA) dated June 15, 2001, received June 18, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Children's Advil Cold (100 mg per 5 ml ibuprofen and 15 mg per 5 ml pseudoephedrine hydrochloride) Suspension, 4 fl. oz., Grape Flavor.

We acknowledge receipt of your submissions dated July 26 and 30, August 3, October 18, November 14 and 21, 2001, and January 7, 11, 14, and 16, February 8 (2 amendments), 14, and 25, March 5, 11, and 19, and April 1, 2, 4, 12, and 18, 2002.

This new drug application provides for the use of Children's Advil Cold (100 mg per 5 ml ibuprofen and 15 mg per 5 ml pseudoephedrine hydrochloride) Suspension for temporary relief of symptoms associated with the common cold, sinusitis, or flu, including nasal congestion, headache, fever, body aches and pains, in children 2 to 11 years of age.

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 labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (4 oz. immediate container and carton labels submitted on April 12, 2002) 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.

We note that you are withdrawing the [redacted] from consideration in this application. If you wish to pursue the [redacted] a supplemental application will be required prior to marketing.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 21-373." 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.

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). Based on the information submitted on October 18, 2001, we are waiving the pediatric study requirement for this action for this application for patients under 2 years of age.

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. Please send one copy to the Division of Over-the-Counter Drug Products. For administrative purposes, this submission should be sent to the NDA and should be identified as a correspondence to approved NDA 21-373.

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 has been transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Elaine Abraham, Project Manager, at (301) 827-2222.

Sincerely yours,

{See appended electronic signature page}

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

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Hilfiker
4/18/02 05:21:39 PM
for C. Ganley

Wiley Chambers
4/18/02 05:25:03 PM
for L. Simon

APPEARS THIS WAY
ON ORIGINAL