DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-374

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 July 24, 2001, received July 30, 2001, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Cold & Sinus Liquigels (200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride capsules).

We acknowledge receipt of your submissions dated August 24, October 18, November 21, and December 13, 2001, and January 24 and 28, February 26, March 11, April 15, 25, 26, and 29, and May 1, 2, 13, 17, 23,and 24, 2002.

This new drug application provides for the use of Advil Cold & Sinus Liquigels (200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride capsules) in patients 12 years of age and older for temporary relief of symptoms associated with the common cold, sinusitis, or flu, including nasal congestion, headache, fever, body aches and pains.

We have completed the review of this application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (16- and 32-count carton labeling submitted on May 13, 2002, and the blister foil labeling submitted on July 24, 2001) 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 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 21-374." 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.

We note the receipt of your submission dated May 24, 2002, in which you agree to provide additional dissolution data collected at (b)(4)---------- speeds by August 1, 2002, to justify the speed of (b)(4)---- that you used in dissolution studies submitted to this NDA. Until the Agency reviews the submitted data and the appropriate (b)(4)---------- is determined, the currently described dissolution test is the approved interim method-

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 12 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 21-374.

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, 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 S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products
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/s/

Charles Ganley
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Lee Simon
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