



NDA 20-589/S-017

Wyeth Consumer Healthcare  
Attention: Barbara Wolfe, Pharm.D.  
Associate Director, Regulatory Affairs  
Five Giralda Farms  
Madison, New Jersey 07940-0871

Dear Dr. Wolfe:

Please refer to your supplemental new drug application dated September 30, 2004, received October 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil (100 mg/5 mL ibuprofen) suspension.

We acknowledge receipt of your submission dated September 30, 2004.

This supplemental new drug application provides for the addition of an organ-specific warning and other warning-related changes to the labeling.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 30, 2005 for the immediate container and carton labels of the Grape, Fruit, and Blue Raspberry flavors respectively.

We have the following additional recommendations to be incorporated at the time of next printing or 180 days:

1. Under the *Directions* section, remove the bold type font from the first two bulleted statements.
2. Under the section entitled, "**Ask a doctor before use if the child has**", revise the order of the bullets as follows:
  - not been drinking fluids
  - lost a lot of fluid due to continued vomiting or diarrhea
  - ulcers
  - bleeding problems
  - problems or serious side effects from taking fever reducers or pain relievers
  - stomach problems that last or come back, such as heartburn, upset stomach or pain high blood pressure, heart or kidney disease or is taking a diuretic
3. Add the "alcohol free" statement to the carton of the fruit flavored product to maintain consistency with the grape and blue raspberry products.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing ibuprofen in the future.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
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.

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Charles Ganley  
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