DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-373/S-003

Wyeth Consumer Healthcare
Attention: Barbara Wolfe, Pharm.D.
Associate Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Wolfe:

Please refer to your supplemental new drug application dated July 7, 2004, received July 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil Cold/Children's Dimetapp Cold & Fever (100mg/5ml ibuprofen and 15mg/5ml pseudoephedrine) Suspension.

We acknowledge receipt of your submissions dated December 9, 2004 and January 7, 2005.

This supplemental new drug application provides revised labeling including new/revised warnings and a revised Statement of Identity.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted July 7, 2004 for Children's Advil Cold Suspension, immediate container labels submitted December 9, 2004 for Children's Dimetapp Cold & Fever Suspension, and carton labels submitted January 7, 2005 for Children's Dimetapp Cold & Fever Suspension), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-373/S-003." Approval of this submission by FDA is not required before the labeling is used.

We are concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. The proposed stomach bleeding warning is acceptable as interim language. However, please note that we will be providing guidance on wording and placement of organ-specific warnings in the labeling of drug products containing ibuprofen in the future.

We recommend the following revisions at the time of next printing.

1. *Children's Advil® Cold*
   Increase the prominence of the dosage form "Liquid Oral Suspension" on the Principal Display Panel (PDP).
2. *Children's Dimetapp® Cold & Fever*
   Include the concentrations of the active ingredients on the PDP in the same manner as Children's Advil® Cold.

We remind you of your agreements for the new trade name "Children's Dimetapp® Cold & Fever" as provided in the supplemental application S-001submissions dated March 13 and 21, 2003. Implementation of this revised labeling (i.e. dosing charts, references) should be provided in the next annual report.

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

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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Leah Christl, Ph.D., Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter 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/

Curtis Rosebraugh
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