**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-373/S-008

Wyeth Consumer Healthcare
Attention: Darcy Gilson
Assistant Director, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Gilson:

Please refer to your supplemental new drug application dated June 3 2008, received June 3, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil Cold® (ibuprofen 100 mg and pseudoephedrine HCL 15 mg/5 ml) suspension.

This supplemental new drug application provides the following changes associated with the Drug Facts label for Children's Advil Cold® suspension:

- The addition of the warning statement "Ask a doctor before use if the child has [bullet] asthma"
- The addition of the warning statement "Do not use [bullet] in a child under 2 years of age"
- A change to the directions modifying the dose (in the dosing chart) for children under 2 years from "ask a doctor" to "do not use"

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text. Only the labels for the referenced package sizes are approved for use under this application.

The FPL must be identical to the enclosed labeling (4 fl oz carton and bottle labels submitted on June 3, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-373/S-008**." Approval of these submissions by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

At the time of next printing or within 180 days, whichever comes first, revise the bulleted statement "do not give longer than 10 days, unless directed by a doctor (See Warnings)" in ***Directions*** to read "do not give longer than 7 days, unless directed by a doctor (See Warnings)." Current labeling

specifies that these products not be taken for more than 10 days. This length of time is appropriate for single ingredient internal analgesic products such as ibuprofen. However, it is not appropriate for internal analgesic products when combined with cold-cough/allergy ingredients to be taken. For example, combination products containing an internal analgesic and nasal decongestant should not be taken more than 7 days (21 CFR 341.85(c)(3)(i)). This revision can be reported 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

*{See appended electronic signature page}*

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

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/s/

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Andrea Segal

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