DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-374/S-007

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

Dear Mr. Napolitano:

Please refer to your supplemental new drug application dated December 21, 2007, received December 26, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil® Cold & Sinus Liqui-gels (ibuprofen 200 mg and pseudoephedrine HCl 30 mg) capsules.

This supplemental new drug application provides for the following changes to the Drug Facts label:

- under the ***Warnings*** section, the addition of the statement "**Ask a doctor before use if you have** [bullet] asthma"
- under the ***Warnings*** section, the addition of the statement "**Do not use** [bullet] in children under 12 years of age"
- a change to the ***Directions*** to read "[bullet] children under 12 years of age: do not use"

We have completed our review of this application. This supplement 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 draft labeling (16-count carton submitted December 21, 2007), and must be formatted in accordance with the applicable requirements of 21 CFR 201.

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 this submission "**FPL for approved supplement NDA 21-374/S-007**." Approval of this submission by FDA is not required before the labeling is used.

In addition, revise your labeling with the following changes within 180 days or at the time of next printing, whichever is sooner:

1. Delete the bulleted statement "pain gets worse or lasts more than 10 days" in the ***Warnings*** section under "**Stop use and ask a doctor if**."

2. Revise the bulleted statement “do not take longer than 10 days, unless directed by a doctor (see Warnings)” in ***Directions*** to read “do not take longer than 7 days, unless directed by a doctor (see Warnings).”

   Note: The labeling changes above are recommended because these products are indicated for the treatment of cold/allergy and, therefore, should not be taken for longer than 7 days without consulting a doctor.

Revised labeling with the above changes should be submitted in the next annual report for this NDA.

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
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

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