DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-771/S-026

Wyeth Consumer Healthcare
Attention: Barbara Wolfe
Associate Director, Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Dr. Wolfe:

Please refer to your supplemental new drug application dated May 9, 2005, received May 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Cold & Sinus (200 mg ibuprofen/ 30 mg pseudoephedrine HCl) tablets.

Your submission of February 15, 2006 constituted a complete response to our November 10, 2005 action letter.

This supplemental new drug application provides for the addition of the warning statement "Ask a doctor or pharmacist before use if you are [bulleted] taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin." to the Drug Facts label.

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 submitted February 15, 2006. We note that the labeling in your supplemental application (028) approved on February 23, 2006 supersedes this application, with the exception of the warning statement noted above.

The final printed labeling (FPL) must be identical to the draft labeling approved on February 23, 2006 under supplement 028 for Advil Cold & Sinus tablets, Advil Cold & Sinus caplets, and Advil Flu & Body Ache with the addition of the identical statement noted above submitted as text for the carton labels under supplement 026 on February 15, 2006, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units approved under supplement 028** 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 supplements NDA 19-771/S-026, S-028**." Approval of this submission by FDA is not required before the labeling is used.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
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/

Andrea Segal

4/17/2006 05:13:34 PM