DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-989/S-070

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

Dear Ms. Brabant:

Please refer to your supplemental new drug application dated December 17, 2007, received December 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil (200 mg ibuprofen) tablets/gelatin coated capsule-shaped tablets.

We also acknowledge receipt of your email dated June 4, 2008 providing further explanation of the representative labeling.

This supplemental new drug application provides for the addition of the warning statement "Ask a doctor before use if you have [bullet] asthma" to the Drug Facts label.

We have completed our review of this supplemental new drug application. This application is approved for the Advil 2-, 10-, 24-count tablet (representative of the 24- and 50-count tablet, caplet, and gelcaplet), 100-count tablet (representative of the 100-, 150-, 165-, 200-, and 225-count tablet, and 100-, 150-, and 200-count caplet, and the 100- and 200-count gelcaplet) and 325-count tablet package sizes, 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 enclosed labeling (2-count tablet front and back pouch labels, 2-count tablet pouch dispenser (50 x 2-count pouches), 10-count tablet loose vial label, 10-count tablet vial card (long), 10-count tablet vial card (short), 325-count tablet immediate container label, and 24-count tablet (representative of the 24- and 50-count tablet, caplet, and gelcaplet) and 100-count tablet (representative of the 100-, 150-, 165-, 200-, and 225-count tablet, and 100-, 150-, and 200-count caplet, and the 100- and 200-count gelcaplet) carton labels submitted December 17, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for all represented stock keeping units 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 18-989/S-070**." 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
Suite 12B05
5600 Fishers Lane
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 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

Enclosure

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

6/11/2008 03:37:35 PM