DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-989/S-067

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 and received April 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil (200 mg ibuprofen) tablets/capsules.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Drug Facts labeling for the 10-count vial blister card and loose vial packages for Advil® Tablets in response to the June 14, and July 15, 2005 supplement request letters and the agreed-upon warning statement approved under supplement 060.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (10-count vial, loose vial, short blister card including Drug Facts booklet, long blister card, 3-pack blister card, and shelf tray submitted April 13, 2007), 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 this submission "**FPL for approved supplement NDA 18-989/S-067**." 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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}

Joel Schiffenbauer, MD
Deputy 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/

Joel Schiffenbauer

5/1/2007 04:12:21 PM