DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-989/S-061

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 August 4, 2005, received August 5, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil (200 mg ibuprofen) tablets/capsules.

We also acknowledge receipt of your submissions dated February 9, and 17, 2006.

The February 17, 2006 submission constituted a complete response to our February 3, 2006 action letter.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for Advil 2-, 24-, 50-, and 100-count package sizes in response to the June 14, and July 15, 2005 supplemental labeling request letters. According to your October 17, 2005 submission, the 100-count package size is representative of the 165- and 225-count package sizes.

We have completed our review of this application, as amended. This application is approved for Advil 2-, 24-, 50-, and 100-count (representative of 165- and 225-count) 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 submitted labeling (100-count immediate container and carton labels submitted August 4, 2005 (representative of the 165- and 225-count), 2-count pouch submitted December 5, 2005, and 50- and 24-count carton and immediate container labels submitted February 17, 2006), and must be in the "Drug Facts" format (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-061**". 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 the requirements for an approved NDA set forth under 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

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