DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-402/S-018

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 9, 2005, received August 12, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Liquigels (200 mg ibuprofen capsules) and Advil Migraine (200 mg ibuprofen) capsules.

We also acknowledge receipt of your submissions dated November 1, 2005 and January 26, 2006.

This supplemental new drug application provides for revisions to the Drug Facts label and Principal Display Panel for the 2-, 4-, 20-, and 80-count package sizes for Advil Liquigels and the 20- and 80-count package sizes for Advil Migraine in response to the June 14 and July 15, 2005 supplemental labeling request letters. According to your November 1, 2005 submission, the Advil Liquigels 80-count package size is representative of the 40-, 135-, and 180-count package sizes, and the Advil Migraine 20-count bottle label is representative of the 40- and 80-count bottle labels and the Advil Migraine 80-count carton label is representative of the 40-count carton label.

We have completed our review of this application. This application is approved for the Advil Liquigels 2-, 4-, 20-, and 80-count (representative of 40-, 135-, and 180-count) package sizes, the Advil Migraine 20- count bottle label (representative of 40-, and 80-count bottle labels), the Advil Migraine 20-count carton, and the Advil Migraine 80-count carton (representative of the 40 count carton), 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 (Advil Liquigels 80-count carton and immediate container labels submitted August 9, 2005, Advil Liquigels 4-count blister card submitted November 1, 2005, Advil Liquigels 20-count carton label submitted November 1, 2005, Advil Liquigels 2-count pouch submitted January 26, 2006, Advil Migraine 20-count carton and immediate container labels submitted November 1, 2005, and Advil Migraine 80-count carton label submitted November 1, 2005.), 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** 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 20-402/S-018**". 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
Acting 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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