DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-989/S-073

Wyeth Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your supplemental new drug application dated November 19, 2008, received November 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil (200 mg ibuprofen) tablets.

We acknowledge receipt of your submissions dated March 30, April 22, and 30, May 14, and 15, 2009.

This supplemental new drug application (NDA) provides for the revised cardiovascular warning statement "When using this product the risk of heart attack or stroke may increase if you use more than directed or for longer than directed" to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letter.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the Advil 24-count tablet (representative of the 24- and 50-count tablet and caplet) carton label, 100-count tablet (representative of the 100-, 150-, and 200-count tablet and caplet, and the 165- and 225-count tablet) carton label, 100-count tablet (representative of the 24-, 50-, 100-, 150-, and 200-count tablet and caplet, and the 165- and 225-count tablet) immediate container label, 2-count tablet front and back pouch labels, 2-count tablet pouch dispenser (50 x 2-count pouches), 10-count tablet vial label (attached to vial card), 10-count tablet vial card (long), 10-count tablet vial card (short), 10-count tablet loose vial dispenser, and 325-count tablet immediate container submitted on November 19, 2008, 10-count tablet vial label (for use in loose vial dispenser) submitted on April 22, 2009, and the 24-count gel caplet (representative of the 24- and 50-count gel caplet) and 100-count gel caplet (representative of the 100- and 200-count gel caplet) immediate container and carton labels submitted on May 14, 2009.

We remind you of the following agreements listed below:

1. In your submission dated April 22, 2009, you agree to separate the net quantity of contents from the established name on the immediate container label of all stock keeping units within 180 days.

2. In your submission dated May 15, 2009, you agree to revise the statement of identity on the Principal Display Panel 2-count tablet pouch dispenser (50 x 2-count pouches) to appear in bold type and in a size reasonably related to the most prominent printed matter (see 21 CFR 201.61(c)) within 180 days.

We note that any labeling submitted in a subsequent supplemental new drug application should incorporate the revisions listed above.

In addition, we have the following recommendation:

3. Consumers may not be aware that the Drug Facts information is provided on the 2-count tablet pouch dispenser (50 x 2-count pouches). We recommend that you add the statement "See full Drug Facts information on the back of this dispenser" or a similar statement.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and 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}

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

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