DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-944/S-008

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 December 15, 2008, received December 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Children's Advil Chewables (50 mg ibuprofen) chewable tablets.

We also acknowledge receipt of your correspondences dated April 30, and May 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. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the Children's Advil Chewables and Junior Strength Advil Chewables grape-flavored 24-count carton and immediate container labels submitted on December 15, 2008.

We remind you of your agreement, stated in your submission dated May 15, 2009, to revise the statement of identity on the Principal Display Panel on all stock keeping units to appear in bold type and in a size reasonably related to the most prominent printed matter (see 21 CFR 201.61(c)) at the time of next printing.

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

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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