DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-267/S-012

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 January 31, 2008, received January 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Junior Strength Advil (100 mg ibuprofen) tablets.

This supplemental new drug application provides for the addition of the warning statement "Ask a doctor before use if you have [bullet] asthma" to the Drug Facts label.

We have completed our review of this supplemental new drug application. This application is approved for the Junior Strength Advil 24-count package size, 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 (24-count carton label submitted January 31, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66.

In addition, the following revision should be made at the time of next printing or 180 days, whichever comes first:

> Remove the promotional statement "Easy-to-swallow" from the Principal Display Panel. The meaning of this promotional statement is unclear.

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 20-267/S-012**." 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
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}

Andrea Leonard-Segal, MD
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/

Andrea Segal

6/20/2008 08:49:00 AM