DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-402/S-011

Wyeth Consumer Healthcare
Attention: Barbara Wolfe, PharmD
Associate Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Wolfe:

Please refer to your supplemental new drug application dated August 25, 2003, received August 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Liqui-Gels and Advil Migraine (200mg ibuprofen) Capsule.

This supplemental new drug application provides for new and revised warning changes to the immediate container and carton label.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed label (FPL) must be identical to the submitted labeling (carton label and immediate container label submitted on August 25, 2003), and must be formatted with the requirements of 21 CFR 201.66.

In addition, we recommend the following change to be made to the Advil Migraine carton label at the time of next printing or 180 days, whichever comes sooner:

> The bulleted statement "stomach pain occurs with the use of this product" under the heading "**Stop use and ask a doctor if**" should be changed to "stomach pain or upset gets worse or lasts," consistent with the Advil Liqui-Gels label.

The Agency is concerned about the need for organ-specific warnings on OTC drug products containing analgesic/antipyretic active ingredients. The sponsor-proposed stomach bleeding warning statement is acceptable as interim language until the Agency provides guidance on specific wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen and/or NSAIDs in the future. At such time, the warning may need to be revised.

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, HFD-410
FDA
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 Walt Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, MD, MPH
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center of 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/

Curtis Rosebraugh
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