**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-812/S-011

Wyeth Consumer Healthcare
Attention: Lauren Quinn
Associate Director, Regulatory Affairs
Five Giralda Farms
Madison, New Jersey 07940

Dear Ms. Quinn:

Please refer to your supplemental new drug application dated May 20, 2004, received May 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infant's Advil (50 mg ibuprofen per 1.25 ml) oral suspension.

This "Changes Being Effected" supplemental new drug application provides for the addition of new organ-specific warnings to the ***Drug Facts*** label.

We 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) submitted on May 20, 2004, for the 15 ml oral suspension (carton and bottle).

We request that you make the following changes to the carton ***Drug Facts*** label at the time of next printing:

- Vertically align all bulleted statements which appear on multiple lines under the same subheading.
- Remove the second "**Ask a doctor before use if the child has**" subheading from the continued portion of that subheading. The continuation arrow located at the bottom of the first part of this section is sufficient to direct consumers to the adjacent panel.

We are concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. The proposed stomach bleeding warning is acceptable as interim language. However, please note that we will be providing guidance on wording and placement of organ-specific warnings in the labeling of drug products containing NSAIDs in the future.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

*{See appended electronic signature page}*

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Charles Ganley

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