DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-944/S-002
NDA 20-944/S-003

Wyeth Consumer Healthcare
Attention: Barbara Wolfe, PharmD.
Associate Director, Regulatory Affairs
Five Giralda Farms
Madison, New Jersey 07940

Dear Dr. Wolfe:

Please refer to your supplemental new drug application dated June 29, 2004, received July 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Junior Strength Advil (100 mg ibuprofen) chewable tablets and Children's Advil (50 mg ibuprofen) chewable tablets (S-002). We also refer to your supplemental new drug application dated November 16, 2004, received November 17, 2004, for Children's Advil (50 mg ibuprofen) chewable tablets (S-003).

These "Changes Being Effected" supplemental new drug applications provide for the addition of a "stomach bleeding warning" and a "sore throat warning" to the carton and blister package labeling for the 50 mg chewable tablets (24 count) and the carton and bottle labeling for the 100 mg chewable tablets (24 count).

We have completed our review of these supplemental new drug applications. These applications are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the carton labeling for the 50mg chewable tablets and the carton and bottle labeling for the 100 mg chewable tablets submitted on June 29, 2004, and the draft blister pack labeling for the 50 mg chewable tablets submitted on November 16, 2004.

We recommend that you revise the Declaration of Net Quantity (*i.e.,* "24 chewable tablets") to appear in bold type as described in CFR 201.62(g), on the carton for the 100 mg product, and the carton for the 50 mg product at the time of next printing.

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 ibuprofen 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}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V

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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