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ATTACHMENT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-429/S-008

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 May 28, 2004, received May 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Orudis KT (12.5 mg ketoprofen) tablets.

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 28, 2004, for the 24 count tablets (carton and bottle) and 100 count tablets (carton and bottle).

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

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

/s/

Charles Ganley
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