DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-754/S-027
NDA 19-816/S-010

Wyeth Pharmaceuticals
P.O. Box 8299
Philadelphia, PA 19101

Attention: Valerie Heisterkamp
Manager, Worldwide Regulatory Affairs

Dear Ms. Heisterkamp:

Please refer to your supplemental new drug applications dated August 9, 2005, received August 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products.

NDA #	Supplement #	Drug
18-754	S-027	Orudis (ketoprofen capsules)
19-816	S-010	Oruvail (ketoprofen extended-release capsules)

These "Changes Being Effected" supplemental new drug applications were submitted in response to the Agency's letter dated June 14, 2005, requiring class labeling language for all non-selective non-steroidal anti-inflammatory drugs (NSAIDS), to include a boxed warning to address possible cardiovascular risks as well as known gastrointestinal risks, revised **CONTRAINDICATIONS, WARNINGS** and **PRECAUTIONS** sections of the package insert, and a **MedGuide** for NSAIDS.

We have completed our review of these applications and they are approved, 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, and include the revisions indicated, to the enclosed labeling text for the package insert and MedGuide. The revisions were agreed upon during a December 12, 2005, teleconference. These revisions are terms of the approval of this application.

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 NDAs 18-754/S-027 and 19-816/S-010."** Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Paul Balcer, Regulatory Project Manager, at (301) 796-1173.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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