DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-816/S-011

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

Attention: Valerie Heisterkamp
Manager, Global Regulatory Affairs

Dear Ms. Heisterkamp:

Please refer to your supplemental new drug application dated February 5, 2007, received February 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oruvail® (ketoprofen) extended-release capsules.

This "Changes Being Effected" supplemental new drug application provides for the NSAID Medication Guide class-labeling change adding a footnote regarding Vicoprofen to the "NSAID Medicines That Need A Prescription" table, in response to our January 5, 2007, supplement request letter.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for package insert and Medication Guide) submitted on February 5, 2007, with one minor editorial revision incorporated into the enclosed labeling to correct the misspelling of "below" in the "Pediatric Use" subsection of the PRECAUTIONS section.

We note that you have submitted content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format.

Within 21 days of the date of this letter, submit content of labeling in SPL format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert and Medication Guide. For administrative purposes, designate this submission as "**Content of Labeling for Approved NDA 19-816/S-011**." Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

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: Package Insert with Medication Guide

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

/s/

Sharon Hertz
7/31/2007 11:13:59 AM
signing for Bob Rappaport, M.D.