



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-754/S-026

Wyeth Pharmaceuticals
Attention: Tracy Rockney, Director
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19022-8299

Dear Mr. Rockney:

Please refer to your supplemental new drug application dated August 14, 1998, received August 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Orudis (ketoprofen) Capsules, NDA 18-754 and Oruvail (ketoprofen) Extended-Release Capsules.

We acknowledge receipt of your submission dated June 23, 2003, received June 27, 2003.

This supplemental new drug application provides for addition of a "Geriatric Use" section to the labeling.

We completed our review of this application, as amended. This application is 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 to the submitted labeling (package insert submitted June 26, 2003).

You have informed the Agency that the product is currently not being manufactured and distributed and that the submitted labeling will be used only for future safety reporting.

If a decision is made to begin manufacture of the product in the future, you will then be required to submit a labeling supplement electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Approval of this submission by the FDA is required before the labeling is used.

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 Nancy Halonen, Regulatory Project Manager, at (301) 827-2040.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550
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/

Lee Simon

8/18/03 07:49:50 PM