DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-147/S-028

Pfizer Pharmaceuticals Group
Attention: Phyllis M. Christesen
Regulatory Affairs

Dear Ms. Christesen:

Please refer to your supplemental new drug application dated April 25, 2002, received April 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Feldene (piroxicam) Capsules 10 mg.

This supplemental new drug application provides for geriatric labeling based on spontaneous adverse event reports, published literature, and available clinical data.

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 labeling submitted on April 25, 2002.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this/these submission(s) should be designated "FPL for approved supplement NDA 18-147/S-028." Approval of this submission y FDA is not 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 301-847-2040.

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
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