DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-841/S-020

Pharmacia Corporation
Attention: Susan Tegtmeyer, M.S.
Manager, Global Regulatory Affairs
4901 Searle Parkway
Skokie, Illinois, 60077

Dear Ms.Tegtmeyer:

Please refer to your supplemental new drug application dated December 19, 2002, received December 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daypro (oxyprozin) 600 mg Caplets.

We acknowledge receipt of your submission dated December 19, 2002.

This supplemental new drug application provides for the aligning of labeling language in conformity with the newly approved (November 22, 2002) NDA 20-776 (Daypro ALTA) to provide uniformity and clarity in both labels.

We have completed our review of this application. This application is approved; effective on the date of this letter, for use as recommended in the agreed-upon labeling text of the package insert that was submitted on December 19, 2002.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

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 submission should be designated "FPL for approved supplement NDA 18-841/S-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

In addition, as required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of this product. Submit all proposed materials in draft or mock up form, not final print. Send one copy to this division, the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, and two copies of both the promotional materials and the proposed package insert directly to:

Division of Drug Marketing, Advertising
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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
Office of Drug Evaluation ODE V
Center for Drug Evaluation and Research

Enclosure (FPL)

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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