DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20776

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

Dear Ms. Tegtmeyer:

Please refer to your new drug application (NDA) dated May 19, 1997, received May 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daypro ALTA (oxaprozin potassium) 600mg tablets and subsequent submissions dated April 21, 1998, March 9, 2000, and June 11, 2001.

We acknowledge receipt of your submissions dated April 19, June 14, October 1 and 11, 2002.

This new drug application provides for the use of Daypro ALTA (oxaprozin potassium) 600mg tablets for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text attached to the end of this letter. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted on October 11, 2002, immediate container and carton labels and the labels for hospital unit dose blister submitted on June 14, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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 NDA 20776." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division 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, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Nancy Halonen, Project Manager, at 301-827-2019.

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 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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