CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-988 /S-013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-998/S-013

Pharmacia Corporation
Attention: Frederick F. Piszkiewicz
Senior Manager, CMC
4901 Searle Parkway
Skokie, IL 60077

Dear Mr. Piszkiewicz:

Please refer to your supplemental new drug application dated December 12, 2001, received December 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex (celecoxib) Capsules.

We acknowledge receipt of your submissions dated April 26, July 1, and August 26 and 29, 2002.

Your submission of April 26, 2002, constituted a complete response to our April 12, 2002, action letter.

This supplemental new drug application provides for the addition of a 400 mg strength to the currently approved strength and the addition of certain container/closure systems for celecoxib 400 mg capsules.

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. Accordingly, the supplemental 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 August 29, 2002, and immediate container and carton labeling submitted July 1, 2002).

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 supplement NDA 20-998/S-013." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

Lawrence Goldkind, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Lawrence Goldkind
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