

209985013

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APPLICATION NUMBER:

20-998 /S-013

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Approval Package

APPLICATION NUMBER:

20-998 /S-013

Trade Name: Celebrex Capsules

Generic Name: Celecoxib

Sponsor: Pharmacia Corporation

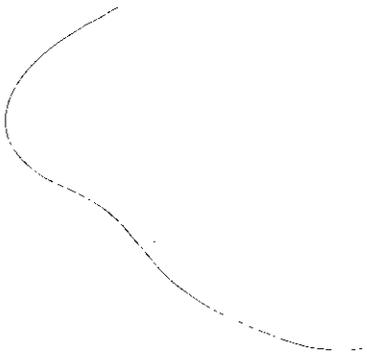
Approval Date: August 29, 2002

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APPLICATION NUMBER:

20-998 /S-013

APPROVAL LETTER





NDA 20-998/S-013

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

Dear Mr. Piszkiwicz:

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.

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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

**APPEARS THIS WAY
ON ORIGINAL**

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/s/

Lawrence Goldkind
8/29/02 10:30:24 PM

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APPLICATION NUMBER:

20-998 /S-013

APPROVABLE LETTER



NDA 20-998/SCF-013

Pharmacia
Attention: Frederick F. Piskiewicz
Manager, CMC
4901 Searle Parkway
Skokie, IL 60077

Dear Mr. Piskiewicz:

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 January 18, 2002, February 7, 2002, and April 5, 2002.

This supplement provides for the addition of a 400-mg strength capsule of Celebrex.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to address the following:

1. Please provide at least three months of accelerated stability data for at least one lot of the proposed drug product (400-mg capsules) packaged in each configuration that is proposed for market. Please include a stability commitment in which the first production batch and annual batches thereafter, packaged in each configuration, will be placed on long-term stability with results provided in the annual report.
2. Please amend the Acceptance Criterion for Appearance in the Specification of the 400-mg capsule such that the description of a specific capsule imprint replaces the words _____
3. Please justify the change in column length in the HPLC method for Assay and determination of degradants provided in this submission _____ with respect to that which was previously established _____
4. Please submit draft labeling revised as follows:
 - a. Delete the following sentence from the CLINICAL PHARMACOLOGY section, Pharmacokinetics, Absorption subsection of the draft package insert: _____
 - b. Delete the following parenthetical expression from the DOSAGE AND



ADMINISTRATION section, Familial adenomatous polyposis (FAP) subsection of the draft package insert: _____

c. Include information (i.e., NDC number) in the HOW SUPPLIED section of the package insert for the proposed package configurations 60-cc HDPE bottles _____

d. Submit draft immediate container and carton labeling for the 400-mg strength.

Please send any common response to supplement 013 of NDA 20-998 and supplements 001 and 002 of NDA 21-156 to both NDAs.

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes prior to approval of this supplemental application.

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}

Wiley A. Chambers, M.D.
Deputy Division 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/

Wiley Chambers
4/12/02 05:28:17 PM

**APPEARS THIS WAY
ON ORIGINAL**