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APPLICATION NUMBER:

20-988 /S-013

APPROVABLE LETTER (S)



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

2. []

3. []

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: "However, in a bioequivalence/comparative bioavailability study, the celecoxib 400-mg capsule was shown to be bioequivalent to two celecoxib 200-mg capsules."
 - b. Delete the following parenthetical expression from the DOSAGE AND



ADMINISTRATION section, Familial adenomatous polyposis (FAP) subsection of the draft package insert: "(1 x 400-mg capsule or 2 x 200-mg capsule)."

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 (14 count) and 290-cc HDPE bottles (180 count).

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
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