DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-998/S-017

Pfizer Inc.
Attention: Kathryn Kross, Director
Worldwide Regulatory Strategy
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Ms. Kross:

Please refer to your supplemental new drug application dated August 9, 2004, received August 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex® (celecoxib) capsules, 100 mg, 200 mg and 400 mg.

We acknowledge receipt of your submissions dated August 9 and September 17, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for additional language to the **PRECAUTIONS – Drug Interactions –** ***Warfarin*** section of the label and a change in the company signature at the end of the label.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The additional language, in italics and double underlined, is as follows:

> "However, in post-marketing experience, *serious* bleeding events, *some of which were fatal*, have been reported, predominantly in the elderly, in association with increases in prothrombin time in patients receiving CELEBREX concurrently with warfarin."

The Division recommends the following language (double underlined) be added:

> In the **ADVERSE REACTIONS** section of the label "**Other serious adverse reactions which occur rarely (estimated <0.1%), regardless of causality:**
>
> ***Nervous system***: Aseptic meningitis, ataxia, suicide, fatal intracranial hemorrhage (see **PRECAUTIONS - Drug Interactions –** ***Warfarin****)"*

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of this application.

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 15 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-016." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
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, please call Ms. Jane A. Dean, RN, MSN, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Center for Drug Evaluation and Research
Office of Drug Evaluation V

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sharon Hertz
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