DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-998/S-027

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: Mojgan Sadrarhami, Pharm.D.
Director, US Regulatory Affairs

Dear Dr. Sadrarhami:

Please refer to your supplemental new drug application dated and received February 29, 2008, 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 18 and 25, May 2(2) and 5, June 4, 13, and 20, September 19, and December 4, 2008.

This supplemental new drug application provides for changes to the following sections of the package insert:

- Dosage and Administration – Special Populations
- Warnings and Precautions – Cardiovascular Effects
- Drug Interactions
- Use in Specific Populations – Nursing Mothers
- Use in Specific Populations – Poor Metabolizers of CYP2C9 Substrates
- Clinical Pharmacology – Pharmacokinetics:Metabolism
- Clinical Studies – Special Studies

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide). Upon receipt, we will transmit that version to the

National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved sNDA 20-998/S-027."

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
Suite 12B05
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, call Parinda Jani, Chief, Project Management Staff, at (301) 796-1232.

Sincerely,

*{See appended electronic signature page}*

Sharon Hertz, M.D.
Deputy Division Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

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/s/

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Sharon Hertz

12/31/2008 03:09:57 PM