DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020998/S-033
NDA 021156/S-003

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Mojgan Sadhrarhami, Pharm.D.
Director, Worldwide Regulatory Strategy
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Sadhrarhami:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 30, 2010, received November 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Celebrex® (celecoxib) Capsules.

Please also refer to your submissions dated January 24, 2011 and February 3, 2011.

These "Prior Approval" supplemental new drug applications (NDA 020098/S-033 and NDA 021156/S-003) provide for removal of the following indication from the **INDICATIONS AND USAGE** Section: "CELEBREX is indicated to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care (e.g., endoscopic surveillance, surgery). It is not known whether there is a clinical benefit from a reduction in the number of colorectal polyps in FAP patients. It is also not known whether the effects of CELEBREX treatment will persist after CELEBREX is discontinued. The efficacy and safety of CELEBREX treatment in patients with FAP beyond six months have not been studied." Also, information pertinent to FAP indication is removed from the **DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, CLINICAL STUDIES,** and **PATIENT COUNSELING INFORMATION** sections of the Package Insert.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, Medication Guide) and include the

labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B - RELEASED

We have received your submission dated August 13, 2010, reporting on the following postmarketing commitments listed in our December 23, 1999, letter.

PMC 431-1: A commitment for a randomized controlled trial in familial adenomatous polyposis (FAP) that will verify and describe the clinical benefit of Celebrex in this population. The Applicant's proposal for a placebo-controlled study of adolescents with FAP aged 12 to 19 years who are genotypically positive but phenotypically negative is acceptable. This study should be completed and results submitted to FDA with due diligence.

PMC 431-2: A commitment for a long-term registry of clinical outcomes in FAP patients. The Applicants proposal for enrolling patients aged 12 years or above to Celebrex 400 BID is acceptable. Eligible patients would include those who are phenotypically positive who a) have not had primary prophylactic surgery, b) have not had secondary surgery, or c) have had both primary and secondary surgery. Time to FAP-related events (FAP-related surgery, gastrointestinal cancer, desmoids, or death) and adverse events will be collected and compared to untreated historical controls. Information collected on registry patients should be submitted to the NDA on annual basis.

We have reviewed your submission and have determined that you are released from the above commitments since you have withdrawn the FAP indication, and the above commitments pertain to the FAP indication.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B - FULFILLED

We have received your submission dated May 4, 2001, containing the final report for the following postmarketing commitment listed in the December 23, 1999, approval letter.

> **PMC 431-5:** A commitment for a submission of biomarker data for each treatment arm (e.g., crypt morphology and apoptotic index, p53 expression, COX messenger RNA/protein expression, etc). for patients on Study 001. Correlation of biomarker findings with the observed reduction in polyp counts should be made for each arm.

We have received your submission dated September 29, 2008, containing the final report for the following postmarketing commitment listed in the December 23, 1999, approval letter.

> **PMC 431-3:** A commitment for a randomized controlled trial in sporadic adenomatous polyps. The Applicants proposal for a placebo-controlled study evaluating the proportion of patients with new adenomas at year 1 and year 3 is generally acceptable. Additional comments regarding the length of patient follow-up will be forthcoming.

We have reviewed your submissions and conclude that the above commitments are fulfilled.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B - OPEN

We also remind you that there is a postmarketing commitment listed in the December 15, 2006, supplement approval letter for NDA 020998/S-021 that is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of

promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 020998 for this drug product and not to NDA 021156. In the future, do not make submissions to NDA 021156 except for the final printed labeling requested above.

If you have any questions, call Jamila Mwidau, Regulatory Project Manager, at (301) 796-4989.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ROBERT L JUSTICE
02/04/2011