DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020571/S-031/S-032/S-033/S-036/S-037

SUPPLEMENT APPROVAL

Pfizer, Inc.
MS 6025-B4125
50 Pequot Avenue, MS
New London, Connecticut 06320

Attention: Ronald Trust, Ph.D., M.B.A., Director
Worldwide Regulatory Strategy

Dear Dr. Trust:

Please refer to your Supplemental New Drug Applications (sNDA) dated December 15, 2005, June 29 and October 27, 2006, September 7, 2007, and September 18, 2009, received December 16, 2005, June 30 and October 30, 2006, September 7, 2007, and September 18, 2009, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Camptosar® (irinotecan HCl) Injection.

We acknowledge receipt of your submissions dated April 14, 2005, July 12 and December 20, 2006, January 24, February 2 and 15, 2007, submitted to S-031.

Prior Approval supplemental new drug application 031 provides for revisions to the **CLINICAL PHARMACOLOGY**, **PRECAUTIONS**, **ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION** sections of the package insert based on results of the post-marketing commitment study, M-6475-0037.

Prior Approval supplemental new drug application 032 provides for revisions to the **CLINICAL PHARMACOLOGY**, **WARNINGS**, **PRECAUTIONS**, and **DOSAGE AND ADMINISTRATION** sections of the package insert to update the UGT1A1 text.

Prior Approval supplemental new drug application 033 provides for inclusion of text related to pulmonary toxicity to the **WARNINGS** and **ADVERSE REACTIONS** sections of the package insert.

Changes Being Effected supplemental new drug application 036 provides for the addition of information on myocardial ischemic events, serum transaminases, hiccups, and megacolon to the **ADVERSE REACTIONS** section of the package insert based on post-marketing data.

Changes Being Effected supplemental new drug application 037 provides for the addition of speech disorders to the **ADVERSE REACTIONS** section of the package insert based on post-marketing data.

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) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

The SPL will be accessible from publicly available labeling repositories.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see 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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Christy Cottrell, Regulatory Project Manager, at (301) 796-4256.

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20571	SUPPL-37	PFIZER INC	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV
NDA-20571	SUPPL-36	PFIZER INC	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV
NDA-20571	SUPPL-33	PFIZER INC	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV
NDA-20571	SUPPL-32	PFIZER INC	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV
NDA-20571	SUPPL-31	PFIZER INC	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV

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

/s/

ANTHONY J MURGO

05/14/2010

Anthony J. Murgo, MD signing for:
Robert L. Justice, M.D., M.S.