DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-571/S-030

US Medical
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Attention: Natalie Touzell
Director, US Regulatory

Dear Ms. Touzell:

Please refer to your supplemental new drug application for CAMPTOSAR® Injection (irinotecan hydrochloride) dated July 13, 2005, received July 14, 2005.

We acknowledge receipt of your submission dated June 1, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for updated patient safety information based on supportive literature. Revisions were made to the **CLINICAL PHARMACOLOGY** section's, **Pharmacokinetics in Special Populations,** *Renal Insufficiency* and the **Drug-Drug Interactions,** ***Neuromuscular blocking agents and Atazanavir sulfate*** subsections; the **CONTRAINDICATIONS** section; the **PRECAUTIONS** section's **General**, *Patients at Particular Risk*, and **Information for Patients** subsections; and the **ADVERSE REACTIONS** section's **Overview of Adverse Events,** *Respiratory* and **Post-Marketing Experience** subsections; and the **OVERDOSAGE** section. In addition, the following minor editorial revision regarding the labeling is requested: the first paragraph of the **DOSAGE AND ADMINISTRATION section,** under the **Dosage in Patients with Reduced UGT1A1 Activity subsection should be bolded:**

"When administered in combination with other agents, or as a single-agent, a reduction in the starting dose by at least one level of CAMPTOSAR should be considered for patients known to be homozygous for the UGT1A1*28 allele (See CLINICAL PHARMACOLOGY and WARNINGS). However, the precise dose reduction in this patient population is not known and subsequent dose modifications should be considered based on individual patient tolerance to treatment (See Tables 10-13)."

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.

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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-571/S-030**." Approval of this submission by FDA is not required before the labeling is used.

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Brenda Atkins, Regulatory Project Manager, at (301) 796-1324.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Robert Justice

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