DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-571/S-024/S-027/S-028

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

Attention: Kristina D. Spranger
Director, U.S. Regulatory Affairs

Dear Ms. Spranger:

Please refer to your supplemental new drug applications dated June 25, 2004 (S-024), May 23, 2005 (S-027), and June 29, 2005 (S-028) received respectively on June 28, 2004 (S-024), May 24, 2005 (S-027), and June 30, 2005 (S-028) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Camptosar® (irinotecan hydrochloride injection), 20 mg/mL.

We acknowledge receipt of your submissions to S-024 dated December 8, 2004, received December 9, 2004 and January 20, 2005, received January 21, 2005.

These supplemental new drug applications provide for the following:

1. S-024 - revisions to the **CLINICAL PHARMACOLOGY** section's, **Pharmacokinetics in Special Populations,** *Hepatic Insufficiency* subsection; the **PRECAUTIONS** section's, **General**, *Patients at Particular Risk*, **Information for Patients, and Laboratory Tests** subsections and the **DOSAGE AND ADMINISTRATION section's, Single-Agent Dosage Schedules/*Dosage Regimens, Dose Modifications* subsections**.
2. S-027 - revisions to update the labeling with regard to pancreatitis incidence in Camptosar® treated patients. The revised section of the labeling pertained to the **ADVERSE REACTIONS** section, **Post-Marketing Experience** subsection.
3. S-028 - revisions to the **DOSAGE AND ADMINISTRATION** section of the label regarding reduction of the starting dose for homozygous patients for the UGT1A1*28 allele.

We have completed our review of these applications. These applications are 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 to the enclosed labeling text for the package insert.

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 supplements NDA 20-571/S-024/S-027/S-028**." Approval of this submission by FDA is not required before the labeling is used.

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, call Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

Sincerely,

{See appended electronic signature page}

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

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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