



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-571/S-023

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

Attention: Kristina Spranger, Senior Manager  
US Regulatory Affairs

Dear Ms. Spranger:

Please refer to your supplemental new drug application dated June 3, 2004, received June 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CAMPTOSAR® Injection (irinotecan hydrochloride) to NDA 20-571.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** section, **Drug-Drug Interactions** subsection of the package insert to include information on drug-drug interactions of irinotecan with anticonvulsants, as well as with ketoconazole and St. Johns Wort.

We completed our review of this application, and it 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 to the enclosed labeling (text for the package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-571/S-023." Approval of this submission by FDA is not required before the labeling is used.

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

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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}*

Richard Pazdur, M.D.  
Director  
Division of Oncology Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Richard Pazdur  
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