DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-571/S-016

Pharmacia & Upjohn Company
Pharmacia Corporation
P.O. Box 800
Peapack, NJ 07977

Attention: Christiane H. Vanderlinden, MS, R.Ph

Dear Ms. Vanderlinen:

Please refer to your supplemental new drug application dated January 11, 2002, received January 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CAMPTOSAR® Injection (irinotecan HCl injection).

We acknowledge receipt of your submissions dated April 25 and April 30, 2002, and May 10, 2002.

This supplemental new drug application provides for revisions to the boxed WARNINGS, CLINICAL STUDIES, WARNINGS, PRECAUTIONS and DOSAGE AND ADMINISTRATION sections of the Package Insert for CAMPTOSAR® Injection.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 10, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten 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-016." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

Your May 10, 2002 submission also included a "Dear Health Care Professional" letter that will accompany the May 2002 package insert to be issued to physicians and others responsible for patient care. We request that you also submit a copy of the letter to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brenda Atkins, Consumer Safety Officer, 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

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

/s/

Richard Pazdur

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