April 20, 2000

NDA 20-571/S-009

Pharmacia & Upjohn
Attention: Christiane H. Vanderlinden
Regulatory Affairs Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Vanderlinden:

Please refer to your supplemental new drug application dated October 19, 1999, received October 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Camptosar® Injection (irinotecan hydrochloride injection) Injection.

We acknowledge receipt of your submissions dated October 29, 1999, December 15, 1999, January 31, 2000, February 9, 2000, February 23, 2000, March 21, 2000, March 28, 2000, April 10, 2000, and April 14, 2000. The user fee goal date for this application is April 20, 2000.

This supplemental new drug application provides for the use of Camptosar® (irinotecan hydrochloride injection) Injection as a component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum.

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 enclosed 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 enclosed labeling (text for the package insert).

Please submit 20 copies of the FPL as soon as it is available, in no case 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-009." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in the Approval Letter dated October 22, 1998. This commitment, along with the completion date agreed upon, is listed below.

- Study M/6475/0017 was to provide a determination of the biliary index in patients with hepatic compromise. The final study report was to have been submitted within approximately 2 years of the approval date. According to your annual report submission dated September 2, 1999, your projected date for a final report is August 2000.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy 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 J. Atkins, Project Manager, at 301-594-5766.

Sincerely yours,

/s/ 4-20-00
Robert L. Justice, M.D.
Deputy Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure