CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20-571/S-008

Trade Name:CAMPTOSAR INJECTION

Generic Name:(irinotecan hydrochloride injection

Sponsor:Pharmacia & Upjohn

Approval Date: October 22, 1998

INDICATION: Provides for the use of Camptosar Injection for treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy

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APPLICATION: NDA 20-571/S-008

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Approvable Letter			X	
Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI			X	
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence	X			

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Application Number:NDA 20-571/S-008

APPROVAL LETTER

NDA 20-571/S-008

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, Michigan 49001

OCT 22 1998

Attention: John S. Walker
Regulatory Affairs Manager

Dear Mr. Walker:

Please refer to your supplemental new drug application dated April 17, 1998, received April 22, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Camptosar (irinotecan hydrochloride injection) Injection.

We acknowledge receipt of your submissions dated May 29, July 15 and 24, August 18 and 28, and September 18, 1998. The user fee goal date for this application is October 22, 1998.

This supplemental new drug application provides for the use of Camptosar Injection for treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.

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 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). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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-008." Approval of this submission by FDA is not required before the labeling is used.

This NDA was approved under the regulations for accelerated approval of new drugs for serious or life-threatening illnesses, specifically, 21 CFR 314.510. Approval of this

supplement fulfills your commitments made under 21 CFR 314.510.

We remind you of your Phase 4 commitments specified in the Approval Letter dated June 14, 1996. We acknowledge receipt of your annual report dated June 29, 1998 that updated these commitments. Some of the commitments have been fulfilled. The following commitments have not been fulfilled. We expect these studies to be completed and the results submitted to us upon completion.

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 send one copy to the Oncology Drug Products 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

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, contact Patrick Guinn, Project Manager, at (301) 827-1537.

Sincerely,

/S/ 10/22/98

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

cc:
Archival NDA 20-571
HFD-150/Div. Files
HFD-150/RJustice
HFD-150/GWilliams
HFD-150/IChico
HFD-150/RWood
HFD-150/RBarron
HFD-150/PAndrews
HFD-150/SRoy
HFD-150/ARahman
HFD-150/LKieffer
HFD-150/GChen
HFD-150/DSmith
HFD-150/P.Guinn
HFD-150/DPease
HFD-101/RTemple
HFD-101/RBehrman
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-101/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-95/DDMS (with labeling)
HFD-810/DNDC Division Director
DISTRICT OFFICE

Drafted by: pfg/October 5, 1998
Initialed by: DPease/10-6-98
IChico/10-13-98
GWilliams/10-13-98
SRoy/10-6-98
PAndrews/10-6-98
DSmith/10-6-98
GChen/10-6-98
RBarron/10-13-98
RWood/10-13-98
LKieffer/10-13-98
ARahman/10-13-98

F/T by: PGuinn/10-14-98/10-19-98
final: DPease/
RJustice/ RJustice 10/22/98

APPROVAL (AP) -