

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40333

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

Office of Generic Drugs
Division of Chemistry 1
Branch 2 HFD-625

FROM: Michael J. Smela, Jr. Team Leader DATE:1/7/00

NAME/TITLE OF INDIVIDUAL(S):Rosalie Lowe, Reg Affairs
FIRM:Gensia Sicor
PRODUCT NAME:5-FU
TEL #:949-457-2808
Reference:ANDA 40333

Notes of Conversation: I phoned regarding the response (A) (1) in the 12/21/99 amendment. I referred to the assay for RLD lot 1222 and asked her to state (1) the exact date they tested it and (2) how they stored the sample while in their possession. She agreed to provide this information as a telephone amendment and said she would also phone or voice mail to me.

SIGNATURE OF OGD REPRESENTATIVES:

/S/ 1/7/00

Location of Electronic Copy:

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE <i>(Title 21, Code of Federal Regulations, 314)</i>		Form Approved: OMB No. 0910-0001 Expiration Date: April 30, 1994 See OMB Statement on Page 3.	
		FOR FDA USE ONLY	
		DATE RECEIVED	DATE FILED
		DIVISION ASSIGNED	NDA/ANDA NO. ASS.
NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).			
NAME OF APPLICANT Gensia Sicor Pharmaceuticals, Inc.		DATE OF SUBMISSION September 16, 1998	
ADDRESS (Number, Street, City, State and Zip Code) 17 Hughes Irvine, CA 92618		TELEPHONE NUMBER (Include Area Code) (949) 457-2808	
		NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) ANDA No. 40-333	
DRUG PRODUCT			
ESTABLISHED NAME (e.g., USP/USAN) Fluorouracil Injection, USP		PROPRIETARY NAME (if any) Not applicable	
CODE NAME (if any) --		CHEMICAL NAME 5-fluoro-2,4 (1H,3H)-pyrimidinedione	
DOSAGE FORM Sterile injectable solution		ROUTE OF ADMINISTRATION Intravenous	STRENGTH(S) 50 mg/mL
PROPOSED INDICATIONS FOR USE: Fluorouracil is effective in the palliative management of carcinoma of the colon, rectum, breast, stomach and pancreas.			
LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION: DMF DMF			
INFORMATION ON APPLICATION			
TYPE OF APPLICATION (Check One)			
<input type="checkbox"/> THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) <input checked="" type="checkbox"/> THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)			
IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
NAME OF DRUG Fluorouracil Injection		HOLDER OF APPROVED APPLICATION Roche Laboratories	
TYPE SUBMISSION (Check one)			
<input type="checkbox"/> PRESUBMISSION <input checked="" type="checkbox"/> AN AMENDMENT TO A PENDING APPLICATION <input type="checkbox"/> SUPPLEMENTAL APPLICATION <input type="checkbox"/> ORIGINAL APPLICATION <input type="checkbox"/> RESUBMISSION			
SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g. Part 314.70 (B)(2)(iv)) <u>Part 314.96</u>			
PROPOSED MARKETING STATUS (Check one)			
<input checked="" type="checkbox"/> APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) <input type="checkbox"/> APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
**APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE
 OR AN ANTIBIOTIC DRUG FOR HUMAN USE**
(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001
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DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT Gensia Sicor Pharmaceuticals, Inc.	DATE OF SUBMISSION August 31, 1998
ADDRESS (Number, Street, City, State and Zip Code) 17 Hughes Irvine, CA 92618	TELEPHONE NUMBER (Include Area Code) (949) 457-2808
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) ANDA No. to be assigned

DRUG PRODUCT

ESTABLISHED NAME (e.g., USP/USAN) Fluorouracil Injection, USP	PROPRIETARY NAME (if any) Not applicable
CODE NAME (if any) --	CHEMICAL NAME 5-fluoro-2,4 (1H,3H)-pyrimidinedione
DOSAGE FORM Sterile injectable solution	ROUTE OF ADMINISTRATION Intravenous
	STRENGTH(S) 50 mg/mL

PROPOSED INDICATIONS FOR USE:
 Fluorouracil is effective in the palliative management of carcinoma of the colon, rectum, breast, stomach and pancreas.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:

DMF
DMF

INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check One)

THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG Fluorouracil Injection	HOLDER OF APPROVED APPLICATION Roche Laboratories
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TYPE SUBMISSION (Check one)

PRESUBMISSION AN AMENDMENT TO A PENDING APPLICATION SUPPLEMENTAL APPLICATION
 ORIGINAL APPLICATION RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g. Part 314.70 (B)(2)(iv)) Part 314.92

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)

E L E C T R O N I C M A I L M E S S A G E

Date: 11-Jan-2000 12:35pm EST
From: Michael Smela
SMELA
Dept: HFD-625 MPN2 E236
Tel No: 301-827-5848 FAX 301-594-0180

TO: ~~Michelle Dillahunt~~ (~~DILLAHUNTM~~)

CC: Shirley Brown (BROWNS)

Subject: ANDA 40333

Michelle...

I am closing this GSP application for fluorouracil. CMC, EES, Labeling and Bio are OK.

Micro review of the 12/21/99 amendment is pending.

Pls add to AP matrix and advise when micro is done.

ks...Mike