

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**40279**

**MICROBIOLOGY REVIEW**

REVIEW FOR OFFICE OF GENERIC DRUGS  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW OF SUPPLEMENT  
11 August 1998

A. 1. ANDA 40-279

APPLICANT: Fujisawa USA, Inc.  
3 Parkway North, 3rd Floor  
Deerfield, IL 60015-2548

2. PRODUCT NAMES: Fluorouracil Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is a sterile solution for injection. The product is supplied in pharmacy bulk packages containing 50 mg/mL of fluorouracil in 50 and 100 mL vials.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPAL INDICATION:

The product is indicated in the palliative management of carcinoma of the colon, rectum, breast, stomach, and pancreas.

B. 1. DATE OF INITIAL SUBMISSION: 3 October 1997

2. DATE OF AMENDMENT: 16 July 1998 (Subject of this Review)

3. RELATED DOCUMENTS:

DMF #	Owner/Type	Subject
		Active Drug Manufacture
		Melrose Park, IL
		Vials
		Vials
		Vials
		Stoppers

4. ASSIGNED FOR REVIEW: 7 August 1998

C. REMARKS: The product will be manufactured at Fujisawa's Melrose Park, IL facility.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/

Paul Stinavage, Ph.D.

11 August 1998

JTC 8/12/98

cc: Original ANDA 40-279  
HFD-640/J. McVey/A. High/K. Sherrod  
HFD-805/Consult File/Stinavage

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*Microbiologists Review #2*

REVIEW FOR OFFICE OF GENERIC DRUGS  
 OFFICE OF NEW DRUG CHEMISTRY  
 MICROBIOLOGY STAFF  
 MICROBIOLOGIST'S REVIEW OF SUPPLEMENT  
 19 March 1998

A. 1. ANDA 40-279

APPLICANT: Fujisawa USA, Inc.  
 3 Parkway North, 3rd Floor  
 Deerfield, IL 60015-2548

2. PRODUCT NAMES: Fluorouracil Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:  
 The product is a sterile solution for injection. The product is supplied in single dose vials containing 50 mg/mL of fluorouracil in 10 and 20 mL vials.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:  
 The product is indicated in the palliative management of carcinoma of the colon, rectum, breast, stomach, and pancreas.

B. 1. DATE OF INITIAL SUBMISSION: 3 October 1997

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS:

DMF #	Owner/Type	Subject
		Active Drug Manufacture
		Melrose Park, IL
		Vials
		Vials
		Vials
		Stoppers

4. ASSIGNED FOR REVIEW: 9 March 1998

**Fujisawa USA; ANDA 40-279; Fluorouracil Injection, USP; Microbiologist's Review #1**

C. REMARKS: The product will be manufactured at Fujisawa's Melrose Park, IL facility.

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns.

*ISI*

*19 March 1998*

Paul Stinavage, Ph.D.

*JAC 3/27/98*

cc: Original ANDA 40-279  
HFD-640/J. McVey/A. High/K. Sherrod  
HFD-805/Consult File/Stinavage

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*Microbiologist's Review # 1*