

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
40278

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/

11 August 1998

Paul Stinavage, Ph.D.

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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Microbiologist Review #2

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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