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:

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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.

cc: Original ANDA 40-279
HFD-640/J. McVey/A. High/K. Sherrod
HFD-805/Consult File/Stinavage
Redacted 2 pages of trade secret and/or confidential commercial information

Microbiologist reviewed #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:

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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.

[Signature]
19 March 1998
Paul Stinavage, Ph.D.

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

PAGE 2
Redacted 11

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Microbiologist’s Review #1