

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
40278

CORRESPONDENCE

ANDA 40-279

Fujisawa, USA, Inc.
Attention: Laurence R. Meyerson, Ph.D.
3 Parkway North, 3rd Floor
Deerfield, IL 60015- 2548

OCT 27 1997

|||||

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Fluorouracil Injection USP, 50 mg/mL, 10 mL and 20 mL vials

DATE OF APPLICATION: October 3, 1997

DATE OF RECEIPT: October 6, 1997

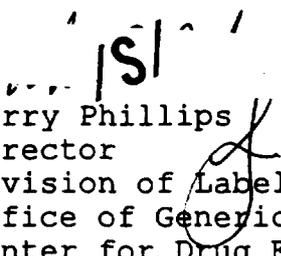
We will correspond with you further after we have had the opportunity to review the application.

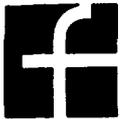
Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Sheila O'Keefe
Project Manager
(301) 827-5848

Sincerely yours,


Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research



FUJISAWA USA, Inc.
 Parkway North Center, Three Parkway North
 Deerfield, Illinois 80015-2548
 Tel. (847) 317-8800 • Telefax (847) 317- 7286

Fujisawa

Labeling review completed
 11/4/97

October 3, 1997

Douglas Sporn, Director
 Office of Generic Drugs
 Metro Park North II, HFD-600, Room 150
 Center for Drug Evaluation and Research
 Food and Drug Administration
 7500 Standish Place
 Rockville, MD 20855-2773

Re: Fluorouracil Injection, USP
50 mg/mL in 10 mL and 20 mL
Glass Vials
Manufacturing Site: Melrose Park, IL
Number of Volumes: 2

Dear Mr. Sporn:

This application is being submitted, in duplicate, as an Abbreviated New Drug Application in accordance with Title I, Sec. 101. Section 505(j) of the Federal Food, Drug and Cosmetic Act to seek marketing clearance for Fluorouracil Injection, USP. Enclosed, for your conveniences, are three copies of the analytical methods and validation section for the drug substance and finished dosage form.

Fujisawa USA, Inc. will manufacture this product at 2020 Ruby Street, Melrose Park, IL 60160. This application contains all the information required describing the manufacturing and control of Fluorouracil Injection, USP 50 mg/mL (10 mL and 20 mL vials), using 6720GC stopper. Since this is a sterile parenteral product, this application contains product specific sterile validation. Applicable general procedural approaches/data may be cross-referenced to Fujisawa USA, Inc., DMF. In addition, this application contains a request for the waiver of *in vivo* bioequivalence studies.

This application has been formatted according to the information in Office of Generic Drugs Policy and Procedure Guide #30-91, April 10, 1991 and letters to industry dated October 14, 1994 and December 24, 1996.

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OCT 06 1997
GENERIC DRUGS

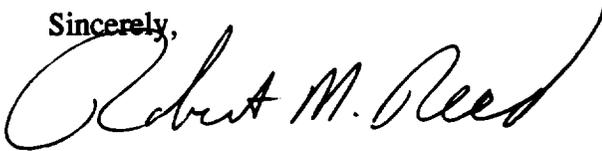
Fluorouracil Injection, USP
October 3, 1997
Page Two

An archival and review copy of this submission are provided for your review. Furthermore, a field copy has been sent to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606 in accordance with 21 CFR §314.94(d)(5). Fujisawa USA, Inc. certifies that the field copy is a true copy of the Abbreviated New Drug Application herewith submitted.

Please be advised that an application for Pharmacy Bulk Package (PBP) is being submitted at the same time as the Single Dose Vial application.

Should you have any questions or require additional information concerning this application, please do not hesitate to contact the undersigned at (847) 317-8985 or Laurence Meyerson, Ph.D. at (847) 317-8642. The facsimile number is (847)317-7286.

Sincerely,



Robert M. Reed
Manager, Regulatory Affairs

L:\WP60\ANDA\08.467

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OCT 06 1997
GENERIC DRUGS

June 3, 1998

NEW CORRESP

Douglas Sporn, Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

NC
NAI
JA 6/8/98

**RE: ANDA 40-279
Fluorouracil Injection, USP
50 mg/mL in 10 mL and 20 mL
Single Dose vials
Manufacturing Site: Melrose Park, IL**

INTENT TO FILE A FACSIMILE AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. Reference is also made to the FDA facsimile dated May 28, 1998. In accordance with 21 CFR 314.120(a)(1), American Pharmaceutical Partners, Inc. is informing you of our **intent to file a facsimile amendment** in response to this facsimile in the near future. Please note that the ownership of this application had been transferred from Fujisawa USA, Inc. to American Pharmaceutical Partners, Inc. effective June 1, 1998.

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Mitchall G. Clark at (310) 264-7768.

Sincerely,



Lincy Michael
Senior Regulatory Scientist

RECEIVED

JUN 04 1998

GENERIC DRUGS

M. Clark
6.5.98

ARCHIVAL



Fujisawa USA, Inc.
Parkway North Center, Three Parkway North
Deerfield, Illinois 60015-2548
Telephone (847) 317-8800 • Telefax (847) 317-7286

Fujisawa

June 1, 1998

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Center for Drug Evaluation and Research
HFD-600, Room 150
7500 Standish Place
Rockville, MD 20855-2773

NEW CORRESP

CC

Handwritten signature

RE: **ANDA 40-279**
Fluorouracil Injection, USP (Single Vial Dose)
Pending Approval

CHANGE IN OWNERSHIP OF AN APPLICATION

Dear Mr. Sporn:

In accordance with the provisions of 21 CFR 314.72, the ownership of the above identified ANDA is being transferred in its entirety, effective June 1, 1998, from Fujisawa USA, Inc. (FUSA) to American Pharmaceutical Partners, Inc (APP).

FUSA affirms that all of the rights to the referenced ANDA have been transferred to APP and that a complete copy of the ANDA including all amendments and FDA correspondence have been provided to APP.

The name and address of the new primary contact person at APP is:

CORPORATE ADDRESS

Mitchall Clark
Senior Director, Regulatory Affairs
American Pharmaceutical Partners, Inc.
2825 Santa Monica Boulevard
Santa Monica, CA 90404
Phone: (310)264-7768

CORRESPONDENCE ADDRESS

Mitchall Clark
Senior Director, Regulatory Affairs
American Pharmaceutical Partners, Inc.
2045 N. Cornell Avenue
Melrose Park, IL 60160
Phone: (708)343-6100

All FDA correspondence should be forwarded to the correspondence address.

Please change your records to reflect this change in the ownership of the ANDA and acknowledge receipt of this letter. All future communications regarding this ANDA should be sent to APP.

Sincerely,

Jerry D. Johnson

Jerry D. Johnson, Ph.D.
Vice President, Regulatory Affairs and Pharmacovigilance

RECEIVED

JUN 02 1998

cc: Mitchall Clark
Senior Director, Regulatory Affairs (APP)



FUJISAWA USA, Inc.
Parkway North Center, Three Parkway North
Deerfield, Illinois 60015-2548
Tel. (847) 317-8800 • Telefax (847) 317-7286

ARCHIVAL
Fujisawa

May 13, 1998

Douglas Sporn, Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT
N/FA

RE: ANDA 40-279
Fluorouracil Injection, USP
50 mg/mL in 10 mL and 20 mL vials

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the facsimile amendment submitted to the FDA on April 30, 1998 and the telephone conversation between Carol Holquist (FDA) and Lincy Michael (Fujisawa) on 5/12/98. As requested by Ms. Holquist, we are sending additional copies of the carton labels.

As discussed on pages 000 00043 and 000 00045 of our facsimile amendment dated April 30, 1998, the 10 mL and 20 mL vials will be packaged in unprinted trays. Each unprinted tray will be properly identified by attaching a vial label to it during the product packaging process. Additionally, the tray will be marked with the quantity of vials per tray. The 10 mL and 20 mL labels included in this submission represent the container and carton labels which should replace pages 000 00067 and 000 00068 of the facsimile amendment dated April 30, 1998.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Should you require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Laurence R. Meyerson, Ph.D. at (847) 317-8642.

Sincerely,

Lincy Michael
Senior Regulatory Scientist

RECEIVED

MAY 14 1998

GENERIC DRUGS



FUJISAWA USA, Inc.
Parkway North Center, Three Parkway North
Deerfield, Illinois 80015-2548
Tel. (847) 317-8800 • Telefax (847) 317-7288

Fujisawa

April 30, 1998

Douglas Sporn, Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

REVIEW

RE: ANDA 40-279
Fluorouracil Injection, USP
50 mg/mL in 10 mL and 20 mL vials
Manufacturing Site: Melrose Park, IL

FACSIMILE AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the attached facsimile dated March 31, 1998 and the telephone conversations between Sheila O'Keefe (FDA) and Lincy Michael (Fujisawa) on 4/3/98 and 4/14/98. We are responding to the observations noted in the facsimile and hereby submit this facsimile amendment. For ease of review, we have organized the FDA observations with the corresponding Fujisawa USA, Inc. responses in the order as delineated in the letter.

As discussed during the telephone conversation on 4/14/98 with Ms. O'Keefe, the ownership of this application will be transferred to American Pharmaceutical Partners, Inc. (APP) on or about June 1, 1998. It is our intent to market this product under APP upon approval. The Final Printed Labeling which is included in this submission reflects APP's name. A letter certifying the change in ownership of this application will be submitted to the FDA when the change occurs.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

RECEIVED

MAY 01 1998

GENERIC DRUGS

Douglas Sporn, Director
ANDA 40-279
Fluorouracil Injection, USP
April 30, 1998

Page 2

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Laurence R. Meyerson, Ph.D. at (847) 317-8642.

Sincerely,

A handwritten signature in cursive script that reads "Lincy Michael". The signature is written in black ink and is positioned below the word "Sincerely,".

Lincy Michael
Senior Regulatory Scientist

5-FU-1-4/3/98



July 16, 1998

Douglas Sporn, Director
Office of Generic Drugs
Metro Park North II, HFD-600, Room 150
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855-2773

NDA 40-279 AMENDMENT
N/AM

**RE: ANDA 40-279
Fluorouracil Injection, USP
50 mg/mL in 10 mL and 20 mL vials
Manufacturing Site: Melrose Park, IL**

MINOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the attached facsimile dated May 28, 1998 and the telephone conversation between Ms. Denice Huie (FDA), Mr. Jim McVey (FDA) and Ms. Lincy Michael (American Pharmaceutical Partners, Inc.) on 6/23/98. We are responding to the observations noted in the facsimile and hereby submit this minor amendment. For ease of review, we have organized the FDA observations with the corresponding responses in the order as delineated in the letter.

Please note that the ownership of this application was transferred from Fujisawa USA, Inc. to American Pharmaceutical Partners, Inc. (APP) effective June 1, 1998. A letter notifying this ownership transfer was sent to the FDA on June 2, 1998.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617.

Sincerely,

Lincy Michael
Senior Regulatory Scientist

RECEIVED

JUL 20 1998

GENERIC DRUGS

Handwritten signature and initials: Raymond V. Mlecko