CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40334

CORRESPONDENCE

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

January 5, 2000

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

N/A M

RE: Fluorouracil Injection, USP
Pharmacy Bulk Package
ANDA 40-334

MINOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application, ANDA 40-334, for Fluorouracil Injection, USP, Pharmacy Bulk Package, which was submitted to the Agency on August 31, 1998. Reference is also made to our amendment dated November 12, 1999. Further reference is made to the Agency's facsimile dated December 15, 1999.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21,* we are hereby amending this application to provide the additional **chemistry** information requested.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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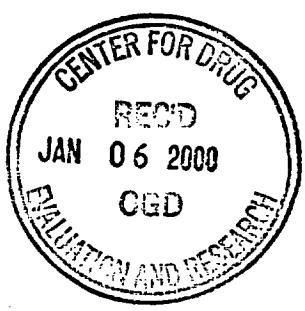
cc: Mr. Thomas Sawyer
Acting District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715



Gensia Sicor Pharmaceuticals, Inc. • 19 Hughes • Irvine CA • 92618-1902 • USA
Phone (949) 455-4700, (800) 729-9991 • Fax (949) 855-8210 • http://www.gensiasicor.com

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

November 23, 1999

Mr. Douglas Sporn
Office of Generic Drugs
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: Fluorouracil Injection, USP
Pharmacy Bulk Package
ANDA 40-334

NEW CORRESPONDENCE

Dear Mr. Sporn:

Reference is made to Gensia Sicor's abbreviated new drug application, ANDA 40-334, for Fluorouracil Injection, USP, Pharmacy Bulk Package, which was submitted to the Agency on August 31, 1998. Reference is also made to our most recent amendment dated November 12, 1999.

Further reference is made to a teleconference call, dated November 18, 1999, between Ms. Teresa Watkins, Division of Labeling and Program Support, FDA and Mr. Dwain Allen, Project Specialist, Regulatory Affairs, Gensia Sicor. Ms. Watkins requested additional clarification regarding the proposed new packaging configuration for this product. Specifically, Ms. Watkins requested a copy of the engineering drawings for the proposed corrugated resealable shipper, which will contain 5 vials (either 50 mL vials or 100 mL vials) per shelf-pack.

We trust you will find the information in this new correspondence satisfactory for your review and approval of the November 12, 1999 amendment. If there are any questions concerning this matter, please do not hesitate in contacting me at (949) 457-2808. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs
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cc: Mr. Thomas Sawyer
Acting District Director
U.S. Food and Drug Administration, Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

NOV 24 1999

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November 12, 1999

ORIG AMENDMENT
N/Amd

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

RE: Fluorouracil Injection, USP
Pharmacy Bulk Package
ANDA 40-334

MINOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application, ANDA 40-334, for Fluorouracil Injection, USP, Pharmacy Bulk Package, which was submitted to the Agency on August 31, 1998. Reference is also made to our amendment dated March 31, 1999. Further reference is made to the Agency's facsimile dated September 29, 1999.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21,* we are hereby amending this application to provide the additional **chemistry and labeling** information requested.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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cc: Mr. Thomas Sawyer
Acting District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

11-0-99

GensiaSicor™
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September 16, 1998

NEW CORRESP
NC

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

RE: **Fluorouracil Injection, USP**
Pharmacy Bulk Package
ANDA 40-334

FACSIMILE AMENDMENT

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application, ANDA 40-334, for Fluorouracil Injection, USP, Pharmacy Bulk Package, which was submitted on August 31, 1998. Reference is also made to the request on September 16, 1998, from Mr. Craig Davis, Office of Generic Drugs, FDA, for a revision to our first page of the Form FDA 356(h). Mr. Davis requested that Gensia Sicor revise the Form FDA 356(h) to eliminate the proprietary name. In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21,* we are hereby amending this application to respond to Mr. Davis' request.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

RECEIVED
SEP 17 1998
GENERIC DRUGS

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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GensiaSicor™
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August 31, 1998

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9/18/98
Gregory S. Davis

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

RE: Fluorouracil Injection, USP
Pharmacy Bulk Package
50 mg/mL
ANDA: Number to be Assigned

Dear Mr. Sporn:

In accordance with Section 314.92 of the *Code of Federal Regulations, Title 21*, we hereby submit an Abbreviated New Drug Application for Fluorouracil Injection, USP, Pharmacy Bulk Package, a parenteral preparation, supplied as:

Strength	Drug Content	How Supplied
50 mg/mL	2500 mg Fluorouracil per vial	50 mL pharmacy bulk polymer vial
50 mg/mL	5 g Fluorouracil per vial	100 mL pharmacy bulk polymer vial

Gensia Sicor's Fluorouracil Injection, USP (50 mg/mL), pharmacy bulk package (50 mL and 100 mL vial), is the generic version of Adrucil® (Fluorouracil Injection, USP) manufactured by Pharmacia and Upjohn, pursuant to ANDA No. 81-225 approved August 28, 1991. The Pharmacia and Upjohn reference listed drug product appears in the FDA listing of Supplement 4 of the *Approved Drug Products with Therapeutic Equivalence Evaluation, 18th Edition.* Our drug product has the same active and inactive ingredients, dosage form, strength, route of administration, and conditions of use as the Pharmacia Upjohn's listed drug product.

RECEIVED
SEP 0 1 1998
GENERIC DRUGS

Gensia Sicor Pharmaceuticals, Inc. • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

Four (4) copies of the proposed labeling have also been provided in **Section V** of the application in both the archival and review copies.

Two (2) exhibit batches of the finished product were manufactured and stability data are presented in **Section XVII** of this application.

The application consists of three (3) volumes and has been formatted in accordance with the Office of Generic Drug's Policy and Procedure Guide #30-91 issued April 10, 1991; and, as modified by FDA's October 14, 1994 letter to all NDA, ANDA, and AADA applicants. Copies are provided as follows:

1) One (1) Archival Copy bound in Blue Jackets
2) One (1) Review Copy bound in Red Jackets

Although a USP monograph exists for the finished product, the method utilized by Gensia Sicor to evaluate the Finished Product for Assay and Impurities differs slightly but has been demonstrated to be equivalent to the USP. Consequently, three (3) additional methods validation packages have been included in this application and are marked "Analytical Methods". These three additional copies are identical to **Section XVI** as presented in the archival and review copies, and have been separately bound in Black Jackets.

A true copy of this application, which was bound in Burgundy Jackets, has been submitted to the U.S. Food and Drug Administration of Irvine, California, Los Angeles District Office.

We trust you will find the information in this application satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

March 31, 1999

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

NDA CRG AMENDMENT
AC

RE: Fluorouracil Injection, USP
Pharmacy Bulk Package
ANDA 40-334

MAJOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application, ANDA 40-334, for Fluorouracil Injection, USP, Pharmacy Bulk Package, which was submitted on August 31, 1998. Reference is also made to the Agency's facsimile dated March 5, 1999. In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21,* we are hereby amending this application to provide the additional information requested.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain K. Allen, Regulatory Project Specialist, at (949) 457-2861. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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APR

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715