Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 | Introduction Type: Post Launch Change | [ ] Final Version | Date: 7/9/2026

PRODUCT INFORMATION

Company Name:	EUGIA US LLC			Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	202669				
Medical Device Class, if applicable:					
DUNS:	968961354				
Proprietary Name (If Applicable) and Established Name:	Fluorouracil Injection USP				
Selling Unit NDC:	55150-498-01	Unit of Use NDC:	55150-498-01	UPC:	355150498017
UDI		CVX Code:		MVX Code:	
Description:	Fluorouracil Injection USP 2.5g/50mL				
Active Ingredient(s):	Fluorouracil Injection USP				
URL for Additional Product Information:	https://eugiaus.com/products/				
Address:	279 Princeton-Hightstown Road		Address 2:		
City:	East Windsor	State:	NJ	Zip:	08520
Key Contact:		Email:			
Phone Number:	888-238-7880	Fax:	732-355-9449		
Product Therapeutic Classification:	ANTIMETABOLITE				

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product…	Direct-Ship Only
a legend device?	No	Is the Product…	
if yes, enter class #		Orphan Drug Status	
a product kit?	No		
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	Yes		
opioid?	No		
Cannabinoid?	No	Country of Origin	INDIA
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	1 Vial
Strength:	2.5 g/50 mL
Dosage Form:	Injection
Product Shape:	Vial Pack
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP

II. Generic Equivalent to What Brand?: ANDRUCIL®

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	
Is product exempt from DSCSA?	No		
If yes, select exemption:		GCP:	
Other exemption - Write in:			
Is product repackaged?	No	If yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	Provide source manufacturer for repackaged product	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each		1		00355150498017	
	Box/Carton/Bundle/Inner Pack					
x	Case		30		50355150498012	
	Pallet				70355150498016	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:

Name: Eugia US Customer Service

Number: 888-238-7880

Group E-mail: CustomerService@EugiaUS.com

c. Special regulations for product in any states? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes

Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months

Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?	
	Bottle	1 Box of 1 Vial (55150-498-01)	
x	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	Minimum order quantity?	Yes
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	If Yes, how many of which package type?	
	Vial Powder Sql		Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In	1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer: 1 Vial

(Write-in, e.g. 1 Vial)

HCPCS J-Code:

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.189	2.24	2.05	3.54	16.25568	1
Box/Carton/Bundle/ Inner Pack:						
Case:	9.965	12.402	8.464	9.842	1033.1199	30
Pallet:	830.258	48	40	58.26	111859.2	2400

COST INFORMATION

Regular Cost Per Unit of Sale ($):

Invoice Cost (WAC) ($): $14.65

As of date: 7/13/2026

WHOLESALER USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: Narender Chamala

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?	Yes
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen?	No
Is the product a CA Prop 65 reproductive toxicant?	Yes
Does the product label bear a CA Prop 65 warning?	No
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	Yes
a. UN/Identification Number	UN3082
b. Proper Shipping Name	Environmentally hazardous substances, liquid, n.o.s.
c. DOT Hazard Class	9 - Class 9 - Miscellaneous hazardous material 49 CFR
d. Packing Group	III - Minor Danger
e. Inhalation Hazard?	No
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	Yes
a. UN/Identification Number	3082
b. Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s.
c. DOT Hazard Class	9 - Miscellaneous Dangerous Substances and Articles
d. Packing Group	III - Low danger
e. Inhalation Hazard?	No
Is the product restricted for air shipment? If so, indicate restriction:	No

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?	Yes
RQ Threshold:	500 lb
Is this a marine pollutant?	No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

No (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	No
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	Yes
If yes, indicate which:	Group 1 items (antineoplastic)

Hazardous Waste Identification

EPA Hazardous Waste Code:		Waste Characteristics	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?	No
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	No
Limited Distribution Requirement	
Comments / Details: (For example, iPledge program?)	
REMS:	No
REMS Program Manager Name:	Phone:
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	DEA #:
Site Enrollment Number assigned by Supplier:	NCPDP#:
	NPI #:
Comments	
Registry:	No
Registry Program Contact Name:	Phone:
Comments	

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No	Controlled Substance Code	
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	No
Restricted to hospital, clinics, and physician offices only:	No
Restricted from US territories? (explain in comments)	No
Comments:	

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:	
Is product returnable for credit:	Yes
URL/Link to returns policy:	https://eugiaus.com/policies/return-policy/
Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? Comments?	

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 | Introduction Type: Post Launch Change | [ ] Final Version | Date: 7/9/2026

PRODUCT INFORMATION

Company Name:	EUGIA US LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	202669
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Fluorouracil Injection USP
Selling Unit NDC:	55150-499-01
Unit of Use NDC:	55150-499-01
UPC:	355150499014
UDI	
CVX Code:	
MVX Code:	
Description:	Fluorouracil Injection USP 5g/100 mL
Active Ingredient(s):	Fluorouracil Injection USP
URL for Additional Product Information:	https://eugiaus.com/products/
Address:	279 Princeton-Hightstown Road
Address 2:	
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Email:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	ANTIMETABOLITE

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	Yes
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product…	Direct-Ship Only
Is the Product… Orphan Drug Status	
FDA Approval Status	
Allergens Present	
Country of Origin	INDIA
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION

Size:	1 Vial
Strength:	5 g/100 mL
Dosage Form:	Injection
Product Shape:	Vial Pack
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP

II. Generic Equivalent to What Brand?: ADRUCIL®

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
	Item/Each		1		00355150499014	
	Box/Carton/Bundle/Inner Pack					
	Case		48		50355150499019	
	Pallet				70355150499013	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:

Name:	Eugia US Customer Service
Number:	888-238-7880
Group E-mail:	CustomerService@EugiaUS.com

c. Special regulations for product in any states? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes

Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months

Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale

	Bottle
x	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sgl
	Vial Powder Multi
	Other: Write In

What is the NDC selling unit?

1 Box of 1 Vial (55150-499-01)

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

1 Vial

(Write-in, e.g. 1 Vial)

HCPCS J-Code:

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.43	2.56	2.56	5.12	33.554432	1
Box/Carton/Bundle/ Inner Pack:						
Case:	28.037	17.323	11.417	12.598	2491.5908	48
Pallet:	Sea: 621.822 Air: 621.822	48	40	Sea:46.45 Air: 58.26	Sea:89184. 0	Sea:1008 Air:1008

COST INFORMATION

Regular Cost Per Unit of Sale ($)	
Invoice Cost (WAC) ($)	$29.30
As of date:	7/13/2026

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: Narender Chamala

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?	Yes
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen?	No
Is the product a CA Prop 65 reproductive toxicant?	Yes
Does the product label bear a CA Prop 65 warning?	No
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT?	Yes
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	UN3082
b. Proper Shipping Name	Environmentally hazardous substances, liquid, n.o.s.
c. DOT Hazard Class	9 - Class 9 - Miscellaneous hazardous material 49 CFR
d. Packing Group	III - Minor Danger
e. Inhalation Hazard?	No
Is this product regulated for shipment by IATA?	Yes
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	3082
b. Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s.
c. DOT Hazard Class	9 - Miscellaneous Dangerous Substances and Articles
d. Packing Group	III - Low danger
e. Inhalation Hazard?	No
Is the product restricted for air shipment? If so, indicate restriction:	No

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?	Yes
RQ Threshold:	500 lb
Is this a marine pollutant?	No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

No (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	No
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	Yes
If yes, indicate which:	Group 1 items (antineoplastic)

Hazardous Waste Identification

EPA Hazardous Waste Code:		Waste Characteristics	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?	No
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	No
Limited Distribution Requirement	
Comments / Details: (For example, iPledge program?)	
REMS:	No
REMS Program Manager Name:	Phone:
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	DEA #:
Site Enrollment Number assigned by Supplier:	NCPDP#:
	NPI #:
Comments	
Registry:	
Registry Program Contact Name:	Phone:
Comments	

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No	Controlled Substance Code	
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	No
Restricted to hospital, clinics, and physician offices only:	No
Restricted from US territories? (explain in comments)	No
Comments:	

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:	
Is product returnable for credit:	Yes
URL/Link to returns policy:	https://eugiaus.com/policies/return-policy/
Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? Comments?	

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?