



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

Version 2021 Introduction Type:  New Item  Final Version Date: 07.02.2024

## PRODUCT INFORMATION

Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC) Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 210735/S-002  
 Medical Device Class, if applicable:  
 DUNS: 968961354  
 Proprietary Name (If Applicable) and Established Name:  
 Selling Unit NDC: 55150-270-99 Unit of Use NDC: 55150-270-99 UPC: 355150270996  
 UDI CVX Code: MVX Code:  
 Description: Cyclophosphamide Injection (200 mg/mL) 500 mg/2.5 mL (Mono Pack) - Multiple Dose Vial  
 Active Ingredient(s): Cyclophosphamide Injection  
 URL for Additional Product Information:  
 Address: 279 Princeton-Hightstown Road Address 2:  
 City: East Windsor State: NJ Zip: 08520  
 Key Contact: Phone Number: 888-238-7880 Email: Fax: 732-355-9449  
 Product Therapeutic Classification: Antineoplastic – Alkylating Agent

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range: Cold – between 2 and 8 C (36° – 46° F)  
 Other Temperature Range Requirement (write in): Store at 2 to 8°C (36 to 46°F).  
 Notes:  
 Is this product to be shipped to customers on ice?  Yes  No  
 Is this product to be shipped to customers on dry ice?  Yes  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?  
 Special returns requirements for this product?  No  No  
 d. Store product (unit of sale) upright?  No  No  
 Protect product (unit of sale) from light?  
 e. Shelf life:  
 Initial shelf life at launch (if different): 21 Months

## 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?  No  
 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)?  No

## PRODUCT DESCRIPTION INFORMATION

Size: 1 Vial  
 Strength: (200 mg/mL) 500 mg/2.5 mL (Mono Pack) - MDV  
 Dosage Form: Injection (Liquid)  
 Product Shape: Vial Pack  
 Product Color:  
 Product Imprint:

## ORDER INFORMATION

Unit of Sale:  Bottle,  Box/Carton,  Ampule,  Glass,  Tube,  Vial Liquid Sgl,  Vial Liquid Multi,  Vial Powder Sgl,  Vial Power Multi,  Other: Write In  
 What is the NDC selling unit? 1 Box of 1 Vial (55150-270-99)  
 (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, Case

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: None  
 II. Generic Equivalent to What Brand?: n/a  
 Authorized Generic \*If Authorized Generic, other section fields are not applicable

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Vial  
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 Each,  Gram,  Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?   
 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

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.13226	1.9685	1.7716	3.1496	10.983898	1 Vial
Box/Carton/Bundle/Inner Pack:	2.38071	8.5039	7.7165	3.7795	248.01209	16 Vials
Case:	11.078	18.7	9.055	9.449	1599.985	64 Vials
Pallet:	476.15	48	40	42.8	82176	2560 Vials

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150270996	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	16		30355150270997	
<input checked="" type="checkbox"/> Case	64		50355150270991	
<input checked="" type="checkbox"/> Pallet	2560		70355150270995	

## COST INFORMATION

Regular Invoice Cost (WAC) (\$) \$150.00  
 As of date: 2/21/2024  
 Vendor #:   
 Whsl. Code #:   
 Finline Code:   
 Signature: Narender Chamala



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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?  No
    - Does the product label bear a CA Prop 65 warning?  No
  - c. Contact Hazard?  Yes
  - d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  Yes
  - 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: UN1851
- b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.
- c. DOT Hazard Class: 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132
- 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: 1851
  - b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.
  - c. DOT Hazard Class: 6.1 - Toxic Substances
  - 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?  No
- RQ Threshold:
- 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#

### ADD'L STORAGE INFORMATION

- Is the Product...
- Controlled Substance?  No
  - Controlled by State(s)?  No
  - ARCOS Reportable?  No
  - Schedule No.
- Controlled Substance Code:
- Listed Chemical (List I or II)  No
- If yes, indicate which:
- 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:

### SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

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:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880

Is product returnable for credit:  Yes

URL/Link to returns policy: <http://auomedics.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:



# 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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	
<input type="text"/>	
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	



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

Version 2021 Introduction Type:  New Item  Final Version Date:

## PRODUCT INFORMATION

**Company Name:** Eugia US LLC (f/k/a AuroMedics Pharma LLC) **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 210735/S-002  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 968961354  
**Proprietary Name (If Applicable) and Established Name:** \_\_\_\_\_  
**Selling Unit NDC:** 55150-271-99 **Unit of Use NDC:** 55150-271-99 **UPC:** 355150271993  
**UDI:** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MXV Code:** \_\_\_\_\_  
**Description:** Cyclophosphamide Injection (200 mg/mL) 1 gm/5 ml (Mono Pack) - Multiple Dose Vial  
**Active Ingredient(s):** Cyclophosphamide Injection  
**URL for Additional Product Information:** \_\_\_\_\_  
**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:** Antineoplastic – Alkylating Agent

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Notes: \_\_\_\_\_  
 Is this product to be shipped to customers on ice?  Yes  NO  
 Is this product to be shipped to customers on dry ice?  Yes  NO

**b. Contact for temperature excursion questions:**  
**Name:**   
**Number:**   
**Group E-mail:**

**c. Special regulations for product in any states?**  
 Special returns requirements for this product?  No  No

**d. Store product (unit of sale) upright?**  No  No

**e. Shelf life:**  
 Protect product (unit of sale) from light?  No  No  
 Initial shelf life at launch (if different):  Months  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No  Yes  
 if yes, enter class # a product kit?  No  Yes  
 if yes, list NDCs of component parts reverse numbered?  No  Yes  
 co-licensed?  No  Yes  
 latex-free?  Yes  No  
 preservative-free?  Yes  No  
 correctional institution block?  No  Yes  
 opioid?  No  Yes  
 Cannabinoid?  No  Yes  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes  No  
 If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**  Yes  No  
**Is the Product... Orphan Drug Status**  Yes  No  
**FDA Approval Status**

**Allergens Present**

**Country of Origin**

Is this product covered under the Trade Agreements Act (TAA)?  Yes  No

## PRODUCT DESCRIPTION INFORMATION

**Size:**   
**Strength:**   
**Dosage Form:**   
**Product Shape:**   
**Product Color:**   
**Product Imprint:**

## ORDER INFORMATION

**Unit of Sale**  
 Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Power Multi  
 Other: Write In \_\_\_\_\_

**What is the NDC selling unit?**  
  
 (Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes  No

**If Yes, how many of which package type?**  
 Each  
 Inner/Carton/Pack  
 Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable  
**I. Orange Book Rating:**   
**II. Generic Equivalent to What Brand?:**

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**   
 (Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**  
 Each  
 Gram  
 Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

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

**GLN:**   
**GCP:**   
 If yes, was original product purchased direct from mfr?  Yes  No  
 Provide source manufacturer for repackaged product

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.1763	2.244	2.047	3.543	16.274657	1 vial
Box/Carton/Bundle/Inner Pack:	3.0567	11.6	7.322	4.173	354.43459	15 vials
Case:	7.436	12.598	8.464	9.842	1049.4473	30 vials
Pallet:	508.95	48	40	44.37	85190.4	1920 vials

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150271993	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	15		30355150271994	
<input checked="" type="checkbox"/> Case	30		50355150271998	
<input checked="" type="checkbox"/> Pallet	1920		70355150271992	

## COST INFORMATION

**Regular Invoice Cost (WAC) (\$)**   
 As of date:

**WHOLESALE USE ONLY:**  
**Vendor #:**   
**Whsl. Code #:**   
**Fineline Code:**



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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?  No  
 Does the product label bear a CA Prop 65 warning?  No

c. Contact Hazard?  Yes

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)  Yes

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: UN1851

b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.

c. DOT Hazard Class: 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

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: 1851

b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.

c. DOT Hazard Class: 6.1 - Toxic Substances

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?  No

RQ Threshold:

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#

### 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:

### SDS Hazard Classification

Organic       Corrosive  
 Inorganic       Oxidizer  
 Steroid/Androgen       Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

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:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880

Is product returnable for credit:  Yes

URL/Link to returns policy: <http://auomedics.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:



# 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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	
	ADDITIONAL INFORMATION
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>



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

Version 2021 Introduction Type:  New Item  Final Version Date:

## PRODUCT INFORMATION

**Company Name:** Eugia US LLC (f/k/a AuroMedics Pharma LLC) **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 210735/S-002

**Medical Device Class, if applicable:**

**DUNS:** 968961354

**Proprietary Name (If Applicable) and Established Name:**

**Selling Unit NDC:** 55150-272-01 **Unit of Use NDC:** 55150-272-01 **UPC:** 355150272013

**UDI** **CVX Code:** **MXV Code:**

**Description:** Cyclophosphamide Injection (200 mg/mL) 2 gm/10 ml (Mono Pack) - Multiple Dose Vial

**Active Ingredient(s):** Cyclophosphamide Injection

**URL for Additional Product Information:**

**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:** Antineoplastic – Alkylating Agent

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

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

Temperature Range: Cold – between 2 and 8 C (36° – 46° F)

Other Temperature Range Requirement (write in): Store at 2 to 8°C (36 to 46°F).

Notes:

Is this product to be shipped to customers on ice?  Yes  NO

Is this product to be shipped to customers on dry ice?  Yes  NO

**b. Contact for temperature excursion questions:**

**Name:** Eugia US Customer Service

**Number:** 888-238-7880

**Group E-mail:** [CustomerService@EugiaUS.com](mailto:CustomerService@EugiaUS.com)

**c. Special regulations for product in any states?**

Special returns requirements for this product?  No  No

**d. Store product (unit of sale) upright?**  No  No

**Protect product (unit of sale) from light?**  No  No

**e. Shelf life:**

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No  Yes

If yes, enter class # a product kit?  No  Yes

If yes, list NDCs of component parts reverse numbered?  No  Yes

co-licensed?  No  Yes

latex-free?  Yes  No

preservative-free?  Yes  No

correctional institution block?  No  Yes

opioid?  No  Yes

Cannabinoid?  No  Yes

If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes  No

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**  **Neither**

**Is the Product... Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin**

Is this product covered under the Trade Agreements Act (TAA)?  No  Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 1 Vial

**Strength:** (200 mg/mL) 2 gm/10 ml (Mono Pack) - MDV

**Dosage Form:** Injection (Liquid)

**Product Shape:** Vial Pack

**Product Color:**

**Product Imprint:**

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Power Multi

Other: Write In

**What is the NDC selling unit?** 1 Box of 1 Vial (55150-272-01) (Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes  No

**If Yes, how many of which package type?**

Each

Inner/Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:**

**II. Generic Equivalent to What Brand?:**

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**  (Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

Each

Gram

Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?**  Yes  No

**Is product exempt from DSCSA?**  Yes  No

**If yes, select exemption:**

**Other exemption - Write in:**

**Is product repackaged?**  No  Yes

**Is product sold by manufacturer's exclusive distributor?**  No  Yes

**Has FDA granted waiver/exception/exemption for product?**  No  Yes

**If yes, attach documentation from FDA.**

**GLN:**

**GCP:**

**If yes, was original product purchased direct from mfr?**  Yes  No

**Provide source manufacturer for repackaged product**

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.183	2.559	2.559	5.118	33.52	1 vial
Box/Carton/Bundle/Inner Pack:	2.69	10.826	8.2677	5.708	510.90	12 vials
Case:	10.55	17.322	11.42	12.598	2491.45	48 vials
Pallet:	350.26	48	40	52.75	85190.4	1536 vials

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150272013	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	12		30355150272014	
<input checked="" type="checkbox"/> Case	48		50355150272018	
<input checked="" type="checkbox"/> Pallet	1536		70355150272012	

## COST INFORMATION

**Regular Invoice Cost (WAC) (\$)**

**As of date:**

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**



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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?  No
    - Does the product label bear a CA Prop 65 warning?  No
  - c. Contact Hazard?  Yes
  - d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  Yes
  - 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: UN1851
- b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.
- c. DOT Hazard Class: 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132
- 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: 1851
  - b. Proper Shipping Name: Medicine, liquid, toxic, n.o.s.
  - c. DOT Hazard Class: 6.1 - Toxic Substances
  - 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?  No
- RQ Threshold:
- 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#

### ADD'L STORAGE INFORMATION

- Is the Product...
- Controlled Substance?  No
  - Controlled by State(s)?  No
  - ARCOS Reportable?  No
  - Schedule No.
- Controlled Substance Code:
- Listed Chemical (List I or II)  No
- If yes, indicate which:
- 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:

### SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

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:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-238-7880

Is product returnable for credit:  Yes

URL/Link to returns policy: <http://auomedics.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:





# 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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	
<input type="text"/>	
	ADDITIONAL INFORMATION
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>