



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

Version 2020 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Xiromed LLC"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="210123"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="FLUOROURACIL"/>
Selling Unit NDC:	<input type="text" value="70700-186-23"/>
UDI	<input type="text"/>
Unit of Use NDC:	<input type="text"/>
UPC:	<input type="text" value="370700186237"/>
CVX Code:	<input type="text"/>
MXV Code:	<input type="text"/>
Description:	<input type="text" value="Fluorouracil Injection, USP 500mg/10mL 10x10mL Single-Dose Vials"/>
Active Ingredient(s):	<input type="text" value="FLUOROURACIL"/>
URL for Additional Product Information:	<input type="text"/>
Address:	<input type="text" value="180 Park Ave"/>
City:	<input type="text" value="Florham Park"/>
Key Contact:	<input type="text" value="David Hernandez"/>
Phone Number:	<input type="text" value="844-947-6633"/>
Product Therapeutic Classification:	<input type="text"/>
Application:	<input type="text" value="ANDA"/>
Address 2:	<input type="text" value="Suite 101"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="07932"/>
Email:	<input type="text" value="david.hernandez@xiromed.com"/>
Fax:	<input type="text" value="862-286-0932"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text" value="Steven Yeung"/>
Number:	<input type="text" value="844-947-6633"/>
Group E-mail:	<input type="text" value="steven.yeung@xiromed.com"/>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
<b>e. Shelf life:</b>	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Container closure is not made with natural rubber latex."/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
correctional institution block? opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
Size:	<input type="text" value="10 x 10mL Single-dose vials"/>	Strength:	<input type="text" value="500MG/10ML (50MG/ML)"/>
Dosage Form:	<input type="text" value="INJECTABLE"/>	Product Shape:	<input type="text"/>
Product Color:	<input type="text"/>	Product Imprint:	<input type="text"/>

ORDER INFORMATION	
Unit of Sale	<input type="text" value="1 Box of 10 Vials"/>
What is the NDC selling unit? (Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Minimum order quantity?	<input type="text" value="No"/>
If Yes, how many of which package type?	<input type="text"/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 Vial"/>
Rx billing unit to pharmacy:	<input type="text" value="x"/> Each
(Write-in, e.g. 1 Vial)	<input type="text"/>
	<input type="text"/>
	<input type="text"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
GLN:	<input type="text" value="0370700000007"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
If yes, attach documentation from FDA.	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Box/Case/Bundle/Inner Pack:	0.617	5.197	2.126	2.559	28.273935	1
Case:	16.535	11.024	9.134	8.465	852.36807	24
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00370700186237"/>	<input type="text"/>
<input type="checkbox"/> Box/Case/Bundle/Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Case	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="20370700186231"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$30.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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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  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 Is the product a CA Prop 65 carcinogen?  No  Yes  
 Is the product a CA Prop 65 reproductive toxicant?  No  Yes  
 Does the product label bear a CA Prop 65 warning?  No  Yes
- c. Contact Hazard?  No  Yes
- d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)  No  Yes
- e. Does the product contain DEHP?  No  Yes
- Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  No  Yes

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

- Is this product regulated for shipment by IATA?  
 (if yes, answer a-e below and provide SDS)  No  Yes
- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  
 Cargo  
 Passenger & Cargo

Is this a reportable quantity?  No  Yes

RQ Threshold:

Is this a marine pollutant?  No  Yes

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

### CLASS OF TRADE RESTRICTION:

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

### SDS Hazard Classification

- Organic       Corrosive  
 Inorganic       Oxidizer  
 Steroid/Androgen       Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug?  No  Yes  
 If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

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

### RETURN INSTRUCTIONS

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