



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="210124"/>
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="70700-189-22"/>
UDI	<input type="text"/>
Description:	<input type="text" value="Fluorouracil Injection, USP 5g/100mL 1x100mL Multiple-dose vial"/>
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"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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. Contact for temperature excursion questions:	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"/>
c. Special regulations for product in any states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	<input type="text" value="24"/>
e. Shelf life:	Initial shelf life at launch (if different): <input type="text" value="24"/> Months

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="1 x 100mL multiple-dose vial"/>
		Strength:	<input type="text" value="5GM/100ML (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	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 1 Vial"/>
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="20"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	Inner/ Carton/ Pack
	Case

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?	Rx billing unit to pharmacy:
<input type="text" value="1 Vial"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

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.	Depth	Width	Height	Volume (Cube)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	0.309	2.165	2.165	4.528	21.223755	1
Case:	7.937	11.22	9.055	5.315	539.98859	20
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="00370700189221"/>	<input type="text"/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="20"/>	<input type="text"/>	<input type="text" value="20370700189225"/>	<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="\$25.70"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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

SDS Hazard Classification

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard

Aerosol Class; Identify NFPA Storage Level: _____

Is the product a NIOSH hazardous drug? No Yes
 If yes, indicate which: Group 1 items (antineoplastic)

a. UN/Identification Number _____

b. Proper Shipping Name _____

c. DOT Hazard Class _____

d. Packing Group _____

e. Inhalation Hazard? No Yes

Hazardous Waste Identification

EPA Hazardous Waste Code: _____ Waste Characteristics: _____

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? No Yes

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
 If Yes, is it managed with a pharmacy registry? No Yes
 Website URL: _____

Med Guide Required No Yes

Limited Distribution Requirement No Yes

Comments / Details: (For example, iPledge program?) _____

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

Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity? Yes
 RQ Threshold: 500

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# _____

REMS:

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively:
 Wholesale distributor support: _____
 Provider Name: _____
 Site Enrollment Number assigned by Supplier: _____
 DEA #: _____
 PCPDP#: _____
 NPI #: _____

Comments _____

Registry:

Registry Program Contact Name: _____ Phone: _____

Comments _____

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 Yes

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: No Yes

Restricted to hospital, clinics, and physician offices only: No Yes

Restricted from US territories? (explain in comments) No Yes

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? No Yes

If so, which states? Other requirements? Comments? _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:
