



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="212993"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="Irinotecan Hydrochloride"/>
Selling Unit NDC:	<input type="text" value="70700-169-22"/>
UDI	<input type="text"/>
Description:	<input type="text" value="Irinotecan Hydrochloride Injection USP 40mg/2ml"/>
Active Ingredient(s):	<input type="text" value="Irinotecan Hydrochloride"/>
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"/>
Unit of Use NDC:	<input type="text"/>
UPC:	<input type="text" value="370700169223"/>
CVX Code:	<input type="text"/>
MXV Code:	<input type="text"/>
State:	<input type="text" value="NJ"/>
Address 2:	<input type="text" value="Suite 101"/>
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*	
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?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
e. Shelf life:	<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?	<input type="text" value="No"/>	Size:	<input type="text" value="2mL Vial"/>
if yes, enter class #	<input type="text"/>	Strength:	<input type="text" value="40MG/2ML (20MG/ML)"/>
if yes, list NDCs of component parts	<input type="text"/>	Dosage Form:	<input type="text" value="Injectable"/>
reverse numbered?	<input type="text" value="No"/>	Product Shape:	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Product Color:	<input type="text"/>
latex-free?	<input type="text" value="Yes"/>	Product Imprint:	<input type="text"/>
preservative-free?	<input type="text" value="Yes"/>		
correctional institution block?	<input type="text" value="Yes"/>		
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"/>		
Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>		
Is the Product... Orphan Drug Status	<input type="text"/>		
FDA Approval Status	<input type="text"/>		
Allergens Present	<input type="text" value="Not made with natural rubber latex. Free from Gluten, Lactose, Sweeteners, Soy, and Gelatin"/>		
Country of Origin	<input type="text" value="India"/>		
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 10 Vials"/>
<input 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 checked="" type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="10"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>
<input type="checkbox"/> Vial Power Multi	Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="CAMPTOSAR"/>
<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 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.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:					0	
Case:	0.551	3.1496	7.874	2.559	63.463073	10
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00370700169223"/>	<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="10"/>	<input type="text"/>	<input type="text" value="10370700169220"/>	<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="\$14.54"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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:



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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? No
- 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 No
- d. Does this product require special clean-up instructions? Yes No
(If yes, attach SDS with special instructions.)
- 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)
- 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)
- 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? Yes No

RQ Threshold: Hydrogen Chloride - 2270kg

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



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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</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="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <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="checkbox"/></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>	<p>Return Instructions</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>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	