



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

Version 2021 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION	
Company Name: <input type="text" value="Xiromed LLC"/>	Application: <input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="215634"/>	
Medical Device Class, if applicable: <input type="text"/>	
DUNS: <input type="text" value="080228637"/>	
Proprietary Name (If Applicable) and Established Name: <input type="text" value="PROGESTERONE"/>	
Selling Unit NDC: <input type="text" value="70700-286-22"/>	Unit of Use NDC: <input type="text"/>
UDI <input type="text"/>	UPC: <input type="text" value="370700286227"/>
	CVX Code: <input type="text"/>
	MXV Code: <input type="text"/>
Description: <input type="text" value="Progesterone Injection, USP 500mg/10mL (50mg/mL)"/>	
Active Ingredient(s): <input type="text" value="PROGESTERONE"/>	
URL for Additional Product Information: <input type="text" value="www.xiromed.com"/>	
Address: <input type="text" value="180 Park Ave"/>	Address 2: <input type="text" value="Suite 101"/>
City: <input type="text" value="Florham Park"/>	State: <input type="text" value="NJ"/>
Key Contact: <input type="text" value="Eric Lee"/>	Zip: <input type="text" value="07932"/>
Phone Number: <input type="text" value="973-803-5520"/>	Email: <input type="text" value="eric.lee@xiromed.com"/>
	Fax: <input type="text" value="862-286-0932"/>
Product Therapeutic Classification: <input type="text"/>	

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="David Hernandez"/>
Number:	<input type="text" value="844-947-6633"/>
Group E-mail:	<input type="text" value="david.hernandez@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="No"/>
<b>e. Shelf life:</b>	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/> Months

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

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Carton of 1 Vial"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Glass	
<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="40"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In <input type="text"/>	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating: <input type="text" value="AO"/>	<input type="checkbox"/> Authorized Generic <small>*If Authorized Generic, other section fields are not applicable</small>
II. Generic Equivalent to What Brand?: <input type="text" value="Progesterone Injection USP, 50mg/mL"/>	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="text" value="1 Vial"/>	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<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"/>	GLN: <input type="text" value="0370700000007"/>
Is product exempt from DSCSA? <input type="text" value="No"/>	GCP: <input type="text" value="0370700"/>
If yes, select exemption: <input type="text"/>	
Other exemption - Write in: <input type="text"/>	
Is product repackaged? <input type="text" value="No"/>	If yes, was original product purchased direct from mfr? <input type="text"/>
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>	Provide source manufacturer for repackaged product <input type="text"/>
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>	
If yes, attach documentation from FDA. <input type="text"/>	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.103	0.806	0.651	1.147	0.6018378	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	5.5	4.263	2.899	2.558	31.612882	40
Pallet:					0	

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	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00370700286227"/>	<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="40"/>	<input type="text"/>	<input type="text" value="10370700286224"/>	<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"/>	Invoice Cost (WAC) (\$) <input type="text" value="\$31.29"/>	Vendor #: <input type="text"/>	Whsl. Code #: <input type="text"/>
As of date: <input type="text"/>		Fineline Code: <input type="text"/>	



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																	
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No            Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No            Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<div style="background-color: #2c4e64; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input checked="" type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> Yes            If yes, indicate which: <input type="text"/> Group 2 items (non-antineoplastic that meets a hazard criterion)</p>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard										
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive																
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer																
<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard																
Hazardous Waste Identification																	
EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>																	
REMS or REGISTRY RESTRICTIONS																	
<p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="checkbox"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>																	
RETURN INSTRUCTIONS																	
<p>Contact tel. # if product 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>																	
ADD'L STORAGE INFORMATION																	
<p>Is the Product...</p> <table style="width:100%; border: none;"> <tr> <td style="width: 30%;">Controlled Substance?</td> <td style="width: 10%;"><input type="checkbox"/> No</td> <td style="width: 30%;">Controlled Substance Code</td> <td style="width: 30%;"><input type="text"/></td> </tr> <tr> <td>Controlled by State(s)?</td> <td><input type="checkbox"/> No</td> <td>Listed Chemical (List I or II)</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable?</td> <td><input type="checkbox"/> No</td> <td>If yes, indicate which:</td> <td><input type="text"/></td> </tr> <tr> <td>Schedule No.</td> <td><input type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td><input type="checkbox"/> No</td> </tr> </table>		Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>	Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No	ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>	Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>														
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No														
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>														
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No														
CLASS OF TRADE RESTRICTION:																	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</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>																	
MISCELLANEOUS NOTES and/or Image of Product Barcode:																	
<input type="text"/>																	



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

Version 2021

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"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> 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"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <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="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> 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="text"/> 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:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>