



# 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:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="213317"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="Gemmyly"/>
Selling Unit NDC:	<input type="text" value="70700-152-85"/>
Unit of Use NDC:	<input type="text"/>
CVX Code:	<input type="text"/>
UPC:	<input type="text" value="370700152850"/>
UVI:	<input type="text"/>
MXV Code:	<input type="text"/>
Description:	<input type="text" value="Norethindrone Acetate + EE Caps &amp; FF Caps, 1mg-0.02mg - 3 x 28 Pack"/>
Active Ingredient(s):	<input type="text" value="Norethindrone Acetate And Ethinyl Estradiol"/>
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*	
<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... Direct-Ship Only	<input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Not made with natural rubber latex."/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="Spain"/>
correctional institution block? opioid?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
Cannabinoid?	<input type="text" value="No"/>	Product Description:	Size: <input type="text" value="3 x 28 Pack"/> Strength: <input type="text" value="1mg/0.02mg"/> Dosage Form: <input type="text" value="Soft Gelatin Capsules"/> Product Shape: <input type="text" value="Oval"/> Product Color: <input type="text" value="24 pink active; 4 maroon placebo"/> Product Imprint: <input type="text" value="24 active imprinted XI; 4 placebo imprinted LF"/>
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"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 64 3x28 Packs"/>
<input checked="" 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 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="48"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text"/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Taytulla"/>
<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 Pack of 3x28"/>	<input checked="" type="checkbox"/> 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.	Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.198	4.85	2.6	3.03	38.2083	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	10.45	19.4	15.59	6.06	1832.8228	48
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="00370700152850"/>	<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="48"/>	<input type="text"/>	<input type="text" value="20370700152854"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Invoice Cost (WAC) (\$)	<input type="text" value="\$518.22"/>	Vendor #:	<input type="text"/>
As of date:	<input type="text"/>	Whsl. Code #:	<input type="text"/>
		Fineline Code:	<input type="text"/>

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																													
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <span style="float: right;">No</span></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <span style="float: right;">No</span>            Is the product a CA Prop 65 reproductive toxicant? <span style="float: right;">No</span>            Does the product label bear a CA Prop 65 warning? <span style="float: right;">No</span></p> <p>c. Contact Hazard? <span style="float: right;">No</span></p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <span style="float: right;">No</span></p> <p>e. Does the product contain DEHP? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <span style="float: right;">No</span>            RQ Threshold: <input style="width: 50%;" type="text"/></p> <p>Is this a marine pollutant? <span style="float: right;">No</span></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?            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 style="width: 50%;" type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">SDS Hazard Classification</p> <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 type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/> </td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;">           Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>            If yes, indicate which: <input style="width: 100%;" type="text"/> </td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">Hazardous Waste Identification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;">EPA Hazardous Waste Code: <input style="width: 90%;" type="text"/></td> <td style="width: 40%; border: none;">Waste Characteristics <input style="width: 90%;" type="text"/></td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <span style="float: right;">No</span></p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 50%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <span style="float: right;">No</span></p> <p>Limited Distribution Requirement <span style="float: right;">No</span></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">REMS Program Manager Name: <input style="width: 90%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td colspan="2">Supplier Manages REMS registry exclusively: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td colspan="2">Wholesale distributor support: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Provider Name: <input style="width: 90%;" type="text"/></td> <td>DEA #: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 90%;" type="text"/></td> <td>PCPDP#: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td></td> <td>NPI #: <input style="width: 90%;" type="text"/></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Registry Program Contact Name: <input style="width: 90%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table> </div>	<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	<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/>		Is the product a NIOSH hazardous drug? 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<p>Is the Product...</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Controlled Substance?</td> <td style="width: 10%; text-align: center;">No</td> <td style="width: 30%;">Controlled Substance Code</td> <td style="width: 30%;"><input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Controlled by State(s)?</td> <td style="text-align: center;">No</td> <td>Listed Chemical (List I or II)</td> <td style="text-align: center;">No</td> </tr> <tr> <td>ARCOS Reportable?</td> <td style="text-align: center;">No</td> <td>If yes, indicate which:</td> <td><input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Schedule No.</td> <td><input style="width: 90%;" type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td style="text-align: center;">No</td> </tr> </table>	Controlled Substance?	No	Controlled Substance Code	<input style="width: 90%;" type="text"/>	Controlled by State(s)?	No	Listed Chemical (List I or II)	No	ARCOS Reportable?	No	If yes, indicate which:	<input style="width: 90%;" type="text"/>	Schedule No.	<input style="width: 90%;" type="text"/>	Is it a scheduled listed chemical product?:	No													
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Schedule No.	<input style="width: 90%;" type="text"/>	Is it a scheduled listed chemical product?:	No																										
CLASS OF TRADE RESTRICTION:																													
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">Yes</span></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>																													
RETURN INSTRUCTIONS																													
<p>Control tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 100%;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>																													
MISCELLANEOUS NOTES and/or Image of Product Barcode:																													
<input style="width: 100%; height: 100%;" type="text"/>																													



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

Version 2020

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 #: 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"/>	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>