



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

Version 2021 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
<b>Company Name:</b> <input type="text" value="Xiromed LLC"/> <b>Application:</b> <input type="text" value="ANDA"/> <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="211783"/> <b>Medical Device Class, if applicable:</b> <input type="text"/> <b>DUNS:</b> <input type="text" value="080228637"/> <b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="ESTRADIOL"/> <b>Selling Unit NDC:</b> <input type="text" value="70700-195-35"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="370700195352"/> <b>UDI</b> <input type="text"/> <b>CVX Code:</b> <input type="text"/> <b>MXV Code:</b> <input type="text"/> <b>Description:</b> <input type="text" value="Estradiol Gel 0.1% 1.25mg 30 packets"/> <b>Active Ingredient(s):</b> <input type="text" value="ESTRADIOL"/> <b>URL for Additional Product Information:</b> <input type="text" value="www.xiromed.com"/> <b>Address:</b> <input type="text" value="180 Park Ave"/> <b>Address 2:</b> <input type="text" value="Suite 101"/> <b>City:</b> <input type="text" value="Florham Park"/> <b>State:</b> <input type="text" value="NJ"/> <b>Zip:</b> <input type="text" value="07932"/> <b>Key Contact:</b> <input type="text" value="Eric Lee"/> <b>Email:</b> <input type="text" value="eric.lee@xiromed.com"/> <b>Phone Number:</b> <input type="text" value="973-803-5520"/> <b>Fax:</b> <input type="text" value="862-286-0932"/> <b>Product Therapeutic Classification:</b> <input type="text"/>				<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>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>					
The product is? <input type="text" value="No"/> a legend device? if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> 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"/>		<b>Is the Product... Is the Product... Orphan Drug Status</b> <input type="text" value="Neither"/>  <b>FDA Approval Status</b> <input type="text"/>  <b>Allergens Present</b> <input type="text" value="Not made with natural rubber latex."/>  <b>Country of Origin</b> <input type="text" value="Spain"/>  <b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="text" value="Yes"/>		<b>Direct-Ship Only</b> <input type="text"/> <b>Neither</b> <input type="text"/>  <b>Size:</b> <input type="text" value="30x1.25mg packets"/> <b>Strength:</b> <input type="text" value="0.1%"/> <b>Dosage Form:</b> <input type="text" value="GEL"/>  <b>Product Shape:</b> <input type="text"/> <b>Product Color:</b> <input type="text"/> <b>Product Imprint:</b> <input type="text"/>					
FOR GENERIC DRUG PRODUCTS									
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic <small>*If Authorized Generic, other section fields are not applicable</small> <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Divigel, 0.1%"/>									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/> <b>Is product exempt from DSCSA?</b> <input type="text" value="No"/> If yes, select exemption: Other exemption - Write in: <input type="text"/> <b>Is product repackaged?</b> <input type="text" value="No"/> <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="No"/> <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/> If yes, attach documentation from FDA. <input type="text"/>				<b>GLN:</b> <input type="text" value="0370700000007"/> <b>GCP:</b> <input type="text" value="0370700"/> <b>If yes, was original product purchased direct from mfr?</b> <input type="text"/> <b>Provide source manufacturer for repackaged product</b> <input type="text"/>					
GTIN AND HIBCC PRODUCT INFORMATION									
<b>Saleable Unit of Measure</b> <input checked="" type="checkbox"/> Item/Each <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack <input type="checkbox"/> Case <input type="checkbox"/> Pallet		<b>Saleable Quantity</b> <input type="text" value="1"/> <input type="text" value="24"/>		<b>HIBCC</b> <input type="text"/> <input type="text"/>		<b>GTIN-14</b> <input type="text" value="00370700195352"/> <input type="text" value="10370700195359"/>		<b>Unit of Use GTIN-14</b> <input type="text"/>	
ORDER INFORMATION				PHARMACY ORDER / BILL UNIT					
<b>Unit of Sale</b> <input type="checkbox"/> Bottle <input checked="" type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="text"/> Other: Write In				<b>What is the NDC selling unit?</b> <input type="text" value="1 Box containing 30 sachets"/> <small>(Write-in, e.g. 1 Box of 10 Vials)</small>  <b>Minimum order quantity?</b> <input type="text" value="Yes"/>					
				<b>If Yes, how many of which package type?</b> <input type="text" value="24"/> Each <input type="text"/> Inner/ Carton/ Pack <input type="text"/> Case					
ITEM AND PACKING INFORMATION									
		<b>Weight Lbs.</b>		<b>Dimensions (US msmts.)</b>		<b>Volume (Cube)</b>		<b>Saleable # Pieces</b>	
<b>Item/Each:</b>		0.013		4.016    3.031    1.89		23.006017		1	
<b>Box/ Carton/ Bundle/ Inner Pack:</b>						0			
<b>Case:</b>		1		14.375    10.875    8.25		1289.707		24	
<b>Pallet:</b>						0			
COST INFORMATION				WHOLESALE USE ONLY:					
<b>Regular Cost</b> <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$151.74"/> <b>As of date:</b> <input type="text"/>				<b>Vendor #:</b> <input type="text"/> <b>Whsl. Code #:</b> <input type="text"/> <b>Fineline Code:</b> <input type="text"/>					
*Please provide any additional information on page 2.								Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. <b>Signature:</b> <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"/> Yes</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: #002060; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: none;"> <tr> <td style="border: none;"><input type="checkbox"/> Organic</td> <td style="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="checkbox"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug?            If yes, indicate which: <input type="checkbox"/> Yes  <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?            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:            Wholesale distributor support: <input type="text"/></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="border: none;">Controlled Substance?</td> <td style="border: none;"><input type="checkbox"/> No</td> <td style="border: none;">Controlled Substance Code</td> <td style="border: none;"><input type="text"/></td> </tr> <tr> <td style="border: none;">Controlled by State(s)?</td> <td style="border: none;"><input type="checkbox"/> No</td> <td style="border: none;">Listed Chemical (List I or II)</td> <td style="border: none;"><input type="checkbox"/> No</td> </tr> <tr> <td style="border: none;">ARCOS Reportable?</td> <td style="border: none;"><input type="checkbox"/> No</td> <td style="border: none;">If yes, indicate which:</td> <td style="border: none;"><input type="text"/></td> </tr> <tr> <td style="border: none;">Schedule No.</td> <td style="border: none;"><input type="text"/></td> <td style="border: none;">Is it a scheduled listed chemical product?:</td> <td style="border: none;"><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"/>