



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

Version 2020 Introduction Type:  Post Launch Change  Final Version Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Xiomed LLC"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="212612"/>
Application:	<input type="text" value="ANDA"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="GLYCOPYRROLATE"/>
Selling Unit NDC:	<input type="text" value="70700-166-25"/>
Unit of Use NDC:	<input type="text" value=""/>
UDI	<input type="text" value=""/>
CVX Code:	<input type="text" value=""/>
UPC:	<input type="text" value="370700166253"/>
MX Code:	<input type="text" value=""/>
Description:	<input type="text" value="Glycopyrrolate Injection, USP 0.4 mg/2mL Single Dose Vial"/>
Active Ingredient(s):	<input type="text" value="GLYCOPYRROLATE"/>
URL for Additional Product Information:	<input type="text" value=""/>
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"/>
Zip:	<input type="text" value="07932"/>
Key Contact:	<input type="text" value="Xiomed Regulatory"/>
Email:	<input type="text" value="usregulatory@xiomed.com"/>
Phone Number:	<input type="text" value="844-947-6633"/>
Fax:	<input type="text" value="862-286-0932"/>
Product Therapeutic Classification:	<input type="text" value=""/>

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" value=""/>
Notes	<input type="text" value=""/>
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="Xiomed Quality"/>
Number:	<input type="text" value="844-947-6633"/>
Group E-mail:	<input type="text" value="US-Quality-Xiomed@xiomed.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>	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value=""/>
a legend device?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
if yes, enter class #	<input type="text" value=""/>	FDA Approval Status	<input type="text" value=""/>
a product kit?	<input type="text" value="No"/>	Allergens Present	<input type="text" value=""/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="India"/>
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
latex-free?	<input type="text" value="Yes"/>	Size:	<input type="text" value="25 x 2 mL Single Dose Vials"/>
preservative-free?	<input type="text" value="No"/>	Strength:	<input type="text" value="0.2MG/ML"/>
correctional institution block?	<input type="text" value="Yes"/>	Dosage Form:	<input type="text" value="INJECTABLE"/>
opioid?	<input type="text" value="No"/>	Product Shape:	<input type="text" value=""/>
Cannabinoid?	<input type="text" value="No"/>	Product Color:	<input type="text" value=""/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>	Product Imprint:	<input type="text" value=""/>
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		

ORDER INFORMATION	
Unit of Sale	<input type="text" value="x"/>
What is the NDC selling unit?	<input type="text" value="1 Box of 25 Vials"/>
Box/Carton	<input type="text" value=""/>
Ampule	<input type="text" value=""/>
Glass	<input type="text" value=""/>
Tube	<input type="text" value=""/>
Vial Liquid Sgl	<input type="text" value=""/>
Vial Liquid Multi	<input type="text" value=""/>
Vial Powder Sgl	<input type="text" value=""/>
Vial Power Multi	<input type="text" value=""/>
Other: Write In	<input type="text" value=""/>
Minimum order quantity?	<input type="text" value="Yes"/>
<b>If Yes, how many of which package type?</b>	
<input type="text" value="12"/>	Each
<input type="text" value=""/>	Inner/ Carton/ Pack
<input type="text" value=""/>	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Robinul®"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 Vial"/>
Rx billing unit to pharmacy:	<input type="text" value="x"/>
(Write-in, e.g. 1 Vial)	Each
	Gram
	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" value=""/>
Other exemption - Write in:	<input type="text" value=""/>
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" value=""/>
If yes, attach documentation from FDA.	<input type="text" value=""/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.47	3.5	3.5	1.8	22.05	1
Case:	7.056	7.402	7.402	5.906	323.5874	12
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" value=""/>	<input type="text" value="00370700166253"/>	<input type="text" value=""/>
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input checked="" type="checkbox"/> Case	<input type="text" value="12"/>	<input type="text" value=""/>	<input type="text" value="20370700166257"/>	<input type="text" value=""/>
<input type="checkbox"/> Pallet	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$135.00"/>	Whsl. Code #:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>

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:

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?  No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 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?  No

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

e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  No

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)  No

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?  No

RQ Threshold:

Is this a marine pollutant?  No

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      Controlled Substance Code

Controlled by State(s)?  No      Listed Chemical (List I or II)  No

ARCOS Reportable?  No      If yes, indicate which:

Schedule No.       Is it a scheduled listed chemical product?:  No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

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       Corrosive

Inorganic       Oxidizer

Steroid/Androgen       Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required  No

Limited Distribution Requirement  No

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:



# 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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <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>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><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>