



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

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="212995"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="Deferasirox Tablets, 360mg"/>
Selling Unit NDC:	<input type="text" value="70700-271-30"/>
Individual Unit NDC:	<input type="text" value=""/>
UPC:	<input type="text" value="370700271308"/>
UDI	<input type="text" value=""/>
CVX Code:	<input type="text" value=""/>
MVX Code:	<input type="text" value=""/>
Description:	<input type="text" value="Deferasirox Tablets, 360mg - 30ct Bottle"/>
Active Ingredient(s):	<input type="text" value="Deferasirox"/>
URL for Additional Product Information:	<input type="text" value=""/>
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="973-324-0200"/>
Product Therapeutic Classification:	<input type="text" value="Iron Chelating Agent"/>
State:	<input type="text" value="NJ"/>
Address 2:	<input type="text" value="Suite 101"/>
Email:	<input type="text" value="david.hernandez@xiromed.com"/>
Fax:	<input type="text" value="862-286-0932"/>
Zip:	<input type="text" value="07932"/>

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" 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. Contact for temperature excursion questions:	
Name:	<input type="text" value="Steven Yeung"/>
Number:	<input type="text" value="973-324-0200"/>
Group E-mail:	<input type="text" value="steven.yeung@xiromed.com"/>
c. Special regulations for product in any states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="text" value="No"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only	<input type="text" value=""/>
Is the Product... Neither	<input type="text" value=""/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>
If Unit Dose NDC, indicate NDC here:	<input type="text" value=""/>
Country of Origin	<input type="text" value="India"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	<input type="text" value="30"/>
Strength:	<input type="text" value="360mg"/>
Dosage Form:	<input type="text" value="Tablets"/>
Product Shape:	<input type="text" value="Film-coated, oval biconvex"/>
Product Color:	<input type="text" value="Blue"/>
Product Imprint:	<input 360"="" on="" one="" side"="" type="text" value="Debossed "/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input 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="checkbox"/> Other: Write In
What is the NDC selling unit?	<input type="text" value="1 Bottle of 30"/>
	(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	
	<input type="text" value="24"/> Each
	<input type="text" value="1"/> Inner/Carton/Pack
	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Jadenu"/>
<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=""/>
Rx billing unit to pharmacy:	<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"/>
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:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.12	1.705	3.26	1.705	9.4769015	1
Case:	4.32	7.625	3.375	5.75	147.972656	24
Pallet:						
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION										
Serialized?	If not, when?	Items aggregated?	Level	Soleable Unit	Quantity	GTIN-14	2D			Linear
							X	2D	2D	
<input checked="" type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	Item	<input checked="" type="checkbox"/>	1	00370700271308	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			Case	<input checked="" type="checkbox"/>	24	10370700271305	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			Pallet	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="760.08"/>	Whsl. Code #:	<input type="text" value=""/>
Federal Excise Tax Per Unit of Sale	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>		

For Designated Drop Ship Only Products, Please Use Page 3
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? No
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No
 (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? 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 by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

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	
<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? <input type="text"/> If yes, indicate which: <input type="text"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="text"/>	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS: <input type="text"/> REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="text"/> Wholesale distributor support: <input type="text"/> Provider Name: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/>	DEA #: <input type="text"/> PCPDP #: <input type="text"/> NPI #: <input type="text"/>
Comments <input type="text"/>	
Registry: <input type="text"/> Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments <input type="text"/>	

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:

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"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <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 style="margin-left: 20px;">Name: <input type="text"/></p> <p style="margin-left: 20px;">Phone: <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="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 style="width: 100%; height: 80px;" 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: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/></p> <p style="margin-left: 20px;">Fax: <input type="text"/> Fax #: <input type="text"/></p> <p style="margin-left: 20px;">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:	Return Instructions
<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 style="width: 100%; height: 80px;" 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 style="width: 100%; height: 80px;" 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:	
<input style="width: 100%; height: 80px;" type="text"/>	