

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

				Introduction Type:	Post Launch Change		Final Version			Date:	11/23/	/2020
	SPECIAL HANDLING AND STORAGE REQUIREMENTS*											
Company Name:	Xiromed LLC			Application:	ANDA	a. Temperature – Indi	cate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k	i)(med device):	212976			Tempe	rature Range	Controlled Room -	between 20	and 25 C (68	– 77° F)	
DUNS:	080228637					Other T	emperature Range R	equirement				
Proprietary Name (If Applicable) a		FLUOCINONIDE				(v	rite in)					
Selling Unit NDC:	70700-146-17	Unit of Use NDC:			0146170	Notes						
UDI		CVX Code:		MVX Code:]						
Description:	Fluocinonide Ointment USF	P, 0.05% 60g Tube				Is this p	roduct to be shipped	to customers on ic	e?		No	
Active Ingredient(s):	FLUOC	CINONIDE				Is this p	roduct to be shipped	to customers on di	y ice?		No	
b. Contact for temperature excursion questions:												
URL for Additional Product Inforn						Name:			Steven Yeun			
Address:	180 Park Ave		01-1-1	Address 2: Suite		Numbe			844-947-663			
City:	Florham Park David Hernandez		State: Email:	NJ Zip: david.hernandez@x	07932	Group	E-mail:		steven.yeu	ng@xirom	<u>a.com</u>	
Key Contact: Phone Number:	844-947-6633		Fax:	862-286-0932	iromea.com	c. Special regulations	for product in any	states?			No	
Product Therapeutic Classification			- I ux.	002 200 0002		<u> </u>	returns requirements				No	
Froduct Therapeutic Glassification						Opecial	returns requirements	s for this product:				
	ADDITIONAL PR	ODUCT INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store product (unit	of sale) upright?					
The new decestion			in Only			11		I-) (II-I-10				
The product is? a legend device?	No	Is the Product Direct-Sh Is the Product Neither	nip Only		60 grams	e. Shelf life:	product (unit of sa	le) from light?		ĺ	24	Months
if yes, enter class #	No	Orphan Drug Status	_	Size:	60 grams		helf life at launch (i	f different):			24	Months
a product kit?	No	Orphan Drug Status			0.05%	Illiniais	inen ine at iauntin (i	i dillerentj.				WOILLIS
if yes, list NDCs of	NO	FDA Approval Status		Strength:	0.0070			ORDER INFORM	ATION			
component parts		The state of the s		D	OINTMENT							
reverse numbered?	No			Dosage Form:		Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present					Bottle		1 Box contain	ing 1 Tube		
latex-free?	No	Not made with natural rubber	r latev	Product Shape:		x	Box/Carton		(Write-in, e.g	g. 1 Box of 10	Vials)	
preservative-free?	Yes	Not made with natural rubber	latex.	i roduct onape.			Ampule					
correctional institution block?	Yes			Product Color:			Glass		Minimum or	der quantity	?	Yes
opioid?	No	_					Tube					
Cannabinoid?	No	Country of Origin Spain		Product Imprint:			Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u	nit dose for hospital	In this was direct account on the direct					Vial Liquid Multi Vial Powder Sql		If Yes, how		ch package ty	ype?
scanning? If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	Vee				Vial Powder Sqi Vial Power Multi		48	Each Inner/Carton	/Dools	
Il Offit Dose, indicate NDC fiere.		Trade Agreements Net (1704):	Yes				Other: Write In			Case	rack	
		FOR GENERIC DRUG PRODUCTS				<u>-</u>	Outer: Write III			Ousc		
		TOR GENERIC BROST ROBOCTS							Į.			
			Auth	orized Generic *If Auth	norized Generic, other section		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB				are not applicable					it to pharm	acv.	
II. Generic Equivalent to What Bra				noido e		Rec. sell unit to custo	mer?		Ry hilling ur			
				noids t		Rec. sell unit to custo		1	Rx billing ur			
ii. Generic Equivalent to What Bra				iloido e		Rec. sell unit to custo 1 Tu (Write-in, e.g. 1 Vial)				Each Gram		
ii. Generic Equivalent to What Bra	nd?: Lidex	UG SUPPLY CHAIN SECURITY ACT (DSCSA) IN	FORMATION	ilotas c		1 Tu		I		Each		
	nd?: Lidex					1 Tu	be		х	Each Gram Milliliter		
Does supplier meet DSCSA defini	nd?: Lidex	Yes	FORMATION GLN:	0370700000007		1 Tu	be	AND PACKING IN	х	Each Gram Milliliter		
	nd?: Lidex					1 Tu	be		X	Each Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	nd?: Lidex	Yes				1 Tu	item	Dimensio	X IFORMATION Ons (US msm	Each Gram Milliliter	Volume	# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: Lidex	Yes No	GLN:	037070000007		(Write-in, e.g. 1 Vial)	be		X	Each Gram Milliliter	Volume (Cube)	# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRI	Yes No	GLN:	037070000007		1 Tu	item	Dimensio	X IFORMATION Ons (US msm	Each Gram Milliliter		# Pieces:
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacturer?	Yes No No No	GLN: If Yes, was original direct from mfr	0370700000007		(Write-in, e.g. 1 Vial)	ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter ts.) Height	(Cube)	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	tion of manufacturer?	Yes No	GLN: If Yes, was original direct from mfr	037070000007		(Write-in, e.g. 1 Vial) [Item/Each: Box/Carton/Bundle/	ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter ts.) Height	(Cube)	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacturer?	Yes No No No	GLN: If Yes, was originated from mfr's lif yes, attach do	0370700000007		(Write-in, e.g. 1 Vial)	Weight Lbs.	Dimension Depth 1.85	x IFORMATION Ons (US msm Width 7.126	Each Gram Milliliter tts.) Height	(Cube) 17.124847 0	1
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacturer?	No No No No	GLN: If Yes, was originated from mfr's lif yes, attach do	0370700000007		(Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/Inner Pack:	ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter ts.) Height	(Cube) 17.124847	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacturer?	No No No No No ON ON ON GTIN AND HIBCC PRODUCT INFORMATI	GLN: If Yes, was originated from mfr's lif yes, attach do	0370700000007 inal product purchased ? cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/Inner Pack:	Weight Lbs.	Dimension Depth 1.85	x IFORMATION Ons (US msm Width 7.126	Each Gram Milliliter tts.) Height	(Cube) 17.124847 0 1048.488	1
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	tion of manufacturer? exclusive distributor? n/exemption for product?	Yes	GLN: If Yes, was origing direct from mfr if yes, attach do ON GTIN	0370700000007 inal product purchased ? cumentation from FDA.		Item/Each: Box/Carton/Bundle/Inner Pack: Case:	Weight Lbs.	Dimension Depth 1.85	x IFORMATION Ons (US msm Width 7.126	Each Gram Milliliter tts.) Height	(Cube) 17.124847 0	1
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.13	Dimension Depth 1.85	x IFORMATION Ons (US msm Width 7.126	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	1 48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	inal product purchased ?		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs.	Dimension Depth 1.85	x IFORMATION Ons (US msm Width 7.126	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488	1 48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.13	Dimension Depth 1.85	x IFORMATION ons (US msm Width 7.126	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: CO Regular Cost	Weight Lbs. 0.13 9.5 ST INFORMATION	Dimension Depth 1.85	x IFORMATION ons (US msm Width 7.126 8.4	Each Gram Milliliter ts.) Height 1.299 7.9	(Cube) 17.124847 0 1048.488 0	48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.13 9.5 ST INFORMATION	Dimension Depth 1.85	x FORMATION ons (US msm Width 7.126 8.4 Vendor #: Whsl. Code	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: CO Regular Cost (WAC) (Weight Lbs. 0.13 9.5 ST INFORMATION	Dimension Depth 1.85	x IFORMATION ons (US msm Width 7.126 8.4	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was origidirect from mfr' if yes, attach do	0370700000007 inal product purchased ? ccumentation from FDA.		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: CO Regular Cost	Weight Lbs. 0.13 9.5 ST INFORMATION	Dimension Depth 1.85	x FORMATION ons (US msm Width 7.126 8.4 Vendor #: Whsl. Code	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	48
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	tion of manufacturer? exclusive distributor? n/exemption for product?	No No No No No OTIN AND HIBCC PRODUCT INFORMATION HIBCC	If Yes, was original direct from mfr if yes, attach do ON GTIN 00370	037070000007 inal product purchased ? cumentation from FDA. -14 -7700146170 -7700146177	Unit of Use GTIN-14	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: CO Regular Cost Invoice Cost (WAC) (As of date:	Weight Lbs. 0.13 9.5 ST INFORMATION	Dimension Depth 1.85	x FORMATION ons (US msm Width 7.126 8.4 Vendor #: Whsl. Code	Each Gram Milliliter ts.) Height 1.299	(Cube) 17.124847 0 1048.488 0	48



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

Version 2020 For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
·	Organic Corrosive							
Is the product a CA Prop 65 carcinogen?								
Is the product a CA Prop 65 reproductive toxicant?	Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions?								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No							
e. Does the product contain DEHP?	If yes, indicate which:							
Is this product regulated for shipment by DOT?								
(if yes, answer a-e below and provide SDS)	Hereadow Wests Islanding							
a. UN/Identification Number	Hazardous Waste Identification							
b. Proper Shipping Name	FRAU LANGE L							
c. DOT Hazard Class	EPA Hazardous Waste Code: Waste Characteristics							
d. Packing Group								
e. Inhalation Hazard?	<u> </u>							
Is this product regulated for shipment by IATA?	REMS or REGISTRY RESTRICTIONS							
(if yes, answer a-e below and provide SDS)	Is there a REMS on this product? No							
a. UN/Identification Number	If Yes, is it managed with a pharmacy registry?							
b. Proper Shipping Name	Website URL:							
c. DOT Hazard Class	Website Urt.							
d. Packing Group	— Mad Cride Remined							
e. Inhalation Hazard?	Med Guide Required No							
Is the product restricted for air shipment? If so, indicate restriction:	Limited Distribution Requirement No							
Passenger	Comments / Details: (For example, iPledge program?)							
Cargo								
Passenger & Cargo								
	REMS:							
Is this a reportable quantity? No								
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:							
No (if yes, identify method below)	Provider Name: DEA #:							
Limited Quantity	Site Enrollment Number assigned PCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)								
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry:							
	Registry Program Contact Name: Phone:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Prione:							
	Comments							
Is the Product								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No								
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged:							
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:							
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes								
Restricted to retail pharmacy only:								
	Special regulations or returns requirements for this							
Restricted to hospital, clinics, and physician offices only:	product in certain states?							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
Commonio.								
MISCELL ₁	NEOUS 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				
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:				
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday				
	Priority Overnight receipt available:				
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is 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?				
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure? Is product order for restocking purposes?				