



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*				
Company Name: <input type="text" value="Eugia US LLC (f/k/a AuroMedics Pharma LLC)"/>			Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="216552"/>					Temperature Range <input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/>				
Medical Device Class, if applicable: <input type="text"/>					Other Temperature Range Requirement (write in) <input type="text"/>				
DUNS: <input type="text" value="968961354"/>					Notes <input type="text" value="DO NOT FREEZE"/>				
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Diltiazem Hydrochloride Injection 25 mg per 5 mL"/>			Unit of Use NDC: <input type="text" value="55150-0425-01"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>				
Selling Unit NDC: <input type="text" value="55150-0425-10"/>			UPC: <input type="text" value="355150425105"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>				
UDI <input type="text"/>			CVX Code: <input type="text"/>		b. Contact for temperature excursion questions:				
Description: <input type="text" value="Diltiazem Hydrochloride Injection 25 mg per 5 mL (5 mg/mL)(10 Vials)"/>			MVX Code: <input type="text"/>		Name: <input type="text" value="Kevin Cagnetti"/>				
Active Ingredient(s): <input type="text" value="Diltiazem Hydrochloride"/>					Number: <input type="text" value="732.839.9400 ex 8009"/>				
URL for Additional Product Information: <input type="text" value="eugiaus.com"/>					Group E-mail: <input type="text" value="kcagnetti@EugiaUS.com"/>				
Address: <input type="text" value="279 Princeton-Hightstown Road"/>			Address 2: <input type="text"/>		c. Special regulations for product in any states? <input type="text" value="No"/>				
City: <input type="text" value="East Windsor"/>			State: <input type="text" value="NJ"/>		Special returns requirements for this product? <input type="text" value="No"/>				
Key Contact: <input type="text"/>			Zip: <input type="text" value="08520"/>		d. Store product (unit of sale) upright? <input type="text" value="No"/>				
Phone Number: <input type="text" value="888-238-7880"/>			Fax: <input type="text" value="732-355-9449"/>		Protect product (unit of sale) from light? <input type="text" value="No"/>				
Product Therapeutic Classification: <input type="text" value="Calcium ion influx inhibitor"/>					e. Shelf life: <input type="text" value="24"/> Months				
					Initial shelf life at launch (if different): <input type="text"/>				
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION			ORDER INFORMATION			
The product is? a legend device? <input type="text" value="No"/>			Is the Product... Is the Product... Orphan Drug Status <input type="text" value="Direct-Ship Only"/>			Size: <input type="text" value="10 x 5 mL Single-Dose Vial"/>			
if yes, enter class # <input type="text"/>			FDA Approval Status <input type="text"/>			Strength: <input type="text" value="25 mg per 5 mL"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>			Allergens Present <input type="text"/>			Dosage Form: <input type="text" value="Solution"/>			
co-licensed? <input type="text" value="No"/>			Country of Origin <input type="text" value="India"/>			Product Shape: <input type="text"/>			
latex-free? <input type="text" value="Yes"/>			Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>			Product Color: <input type="text" value="Colorless"/>			
preservative-free? <input type="text" value="Yes"/>						Product Imprint: <input type="text"/>			
correctional institution block? <input type="text" value="No"/>						Unit of Sale			
opioid? <input type="text" value="No"/>						<input checked="" 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 Powder Multi <input type="checkbox"/> Other: Write In			
Cannabinoid? <input type="text" value="No"/>						What is the NDC selling unit? <input type="text" value="1 box of 10 vials"/> (Write-in, e.g. 1 Box of 10 Vials)			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>						Minimum order quantity? <input type="text" value="Yes"/>			
If Unit Dose, indicate NDC here: <input type="text"/>						If Yes, how many of which package type? <input type="text"/> Each <input type="text"/> Inner/ Carton/ Pack <input type="text" value="1"/> Case			
FOR GENERIC DRUG PRODUCTS									
I. Orange Book Rating: <input type="text" value="AP"/>			<input type="checkbox"/> Authorized Generic			*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Cardizem Injection"/>									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>			GLN: <input type="text"/>						
Is product exempt from DSCSA? <input type="text" value="No"/>			GCP: <input type="text"/>						
If yes, select exemption: Other exemption - Write in: <input type="text"/>			If yes, was original product purchased direct from mfr? <input type="text"/>						
Is product repackaged? <input type="text" value="No"/>			Provide source manufacturer for repackaged product <input type="text"/>						
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>									
Has FDA granted waiver/exception/exemption for product? <input type="text"/>									
If yes, attach documentation from FDA. <input type="text"/>									
GTIN AND HIBCC PRODUCT INFORMATION									
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="10"/>				<input type="text" value="00355150425105"/>			
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack									
<input checked="" type="checkbox"/> Case		<input type="text" value="200"/>				<input type="text" value="50355150425100"/>			
<input checked="" type="checkbox"/> Pallet		<input type="text" value="16800"/>				<input type="text" value="70355150425104"/>			
					WHOLESALE USE ONLY:				
Regular Cost					Vendor #: <input type="text"/>				
Invoice Cost (WAC) (\$)					Whsl. Code #: <input type="text"/>				
As of date: <input type="text" value="5/19/2023"/>					Finline Code: <input type="text"/>				

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:



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

Version 2021 Introduction Type: New Item Final Version Date: 14.05.2023

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC)	Application: ANDA	a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216552		Temperature Range: <input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/>	
Medical Device Class, if applicable:		Other Temperature Range Requirement (write in): <input type="text"/>	
DUNS: 968961354		Notes: <input type="text" value="DO NOT FREEZE"/>	
Proprietary Name (If Applicable) and Established Name: Diltiazem Hydrochloride Injection 50 mg per 10 mL		Is this product to be shipped to customers on ice? <input type="text" value="No"/>	
Selling Unit NDC: 55150-0426-10	Unit of Use NDC: 55150-0426-01	Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>	
UDI	UPC: 355150426102	b. Contact for temperature excursion questions:	
Description: Diltiazem Hydrochloride Injection 50 mg per 10 mL (5 mg/mL)(10 Vials)	CVX Code:	Name: Kevin Cagnetti	
Active Ingredient(s): Diltiazem Hydrochloride	MVX Code:	Number: 732.839.9400 ex 8009	
URL for Additional Product Information: eugiaus.com		Group E-mail: kcagnetti@EugiaUS.com	
Address: 279 Princeton-Hightstown Road	Address 2:	c. Special regulations for product in any states?	
City: East Windsor	State: NJ	Special returns requirements for this product? <input type="text" value="No"/>	
Key Contact:	Zip: 08520		
Phone Number: 888-238-7880	Fax: 732-355-9449	d. Store product (unit of sale) upright? <input type="text" value="No"/>	
Product Therapeutic Classification: Calcium ion influx inhibitor		Protect product (unit of sale) from light? <input type="text" value="No"/>	
		e. Shelf life: 24 Months	
		Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	<input type="text"/>	Is the Product... Direct-Ship Only	<input type="text" value="10 x 10 mL Single-Dose Vial"/>
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"/>	FDA Approval Status	<input type="text" value="50 mg per 10 mL"/>
a product kit?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Solution"/>
if yes, list NDCs of component parts	<input type="text"/>	Country of Origin	<input type="text" value="Colorless"/>
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"/>		
preservative-free?	<input type="text" value="Yes"/>		
correctional institution block?	<input type="text" value="No"/>		
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"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 box of 10 vials"/>
<input 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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Liquid Multi	<input type="text"/>
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>
<input type="checkbox"/> Vial Powder Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="text" value="1 Vial"/>	Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<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"/>	GLN:	<input type="text"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>	GCP:	<input type="text"/>
If yes, select exemption:	<input type="text"/>	If yes, was original product purchased direct from mfr?	<input type="text" value="No"/>
Other exemption - Write in:	<input type="text"/>	Provide source manufacturer for repackaged product	<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"/>		
If yes, attach documentation from FDA.	<input type="text"/>		

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.4962	5.31	2.17	2.36	27.194	10
Box/Carton/Bundle/Inner Pack:						
Case:	12.901	14.567	12.008	6.299	1101.824	240
Pallet:	729.69	48	40	42.80	82176.00	12960

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	10		00355150426102	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	240		50355150426107	
<input type="checkbox"/> Pallet	12960		70355150426101	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$68.80	Whsl. Code #:	<input type="text"/>
As of date: 5/19/2023		Fineline Code:	<input type="text"/>



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*			
Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC)		Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216552		Medical Device Class, if applicable:		Temperature Range: <input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/>			
DUNS: 968961354		Proprietary Name (If Applicable) and Established Name: Diltiazem Hydrochloride Injection 125 mg per 25 mL		Other Temperature Range Requirement (write in):			
Selling Unit NDC: 55150-0427-10		Unit of Use NDC: 55150-0427-01		Notes: <input type="text" value="DO NOT FREEZE"/>			
UDI:		CVX Code:		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Description: Diltiazem Hydrochloride Injection 125 mg per 25 mL (5 mg/mL)(10 Vials)		MVX Code:		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
Active Ingredient(s): Diltiazem Hydrochloride		URL for Additional Product Information: eugiaus.com		b. Contact for temperature excursion questions:			
Address: 279 Princeton-Hightstown Road		Address 2:		Name: <input type="text" value="Kevin Cagnetti"/>			
City: East Windsor		State: NJ		Number: <input type="text" value="732.839.9400 ex 8009"/>			
Key Contact:		Email:		Group E-mail: <input type="text" value="kcagnetti@EugiaUS.com"/>			
Phone Number: 888-238-7880		Fax: 732-355-9449		c. Special regulations for product in any states?			
Product Therapeutic Classification: Calcium ion influx inhibitor				Special returns requirements for this product? <input type="text" value="No"/>			
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION			
The product is? a legend device? <input type="text" value="No"/>		Is the Product... Is the Product... Orphan Drug Status: <input type="text" value="Direct-Ship Only"/>		Unit of Sale: <input checked="" type="checkbox"/> Bottle			
if yes, enter class #		FDA Approval Status:		What is the NDC selling unit? <input type="text" value="1 box of 10 vials"/>			
if yes, list NDCs of component parts		Allergens Present:		(Write-in, e.g. 1 Box of 10 Vials)			
reverse numbered? <input type="text" value="No"/>		Country of Origin: <input type="text" value="India"/>		Minimum order quantity? <input type="text" value="Yes"/>			
co-licensed? <input type="text" value="No"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		If Yes, how many of which package type? <input type="text" value="1"/> Each			
latex-free? <input type="text" value="Yes"/>				<input type="text" value="1"/> Inner/ Carton/Pack			
preservative-free? <input type="text" value="Yes"/>				<input type="text" value="1"/> Case			
correctional institution block? <input type="text" value="No"/>							
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?							
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AP"/>		Authorized Generic: <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Cardizem Injection"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN:					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP:					
If yes, select exemption: Other exemption - Write in:		If yes, was original product purchased direct from mfr? <input type="text" value=""/>					
Is product repackaged? <input type="text" value="No"/>		Provide source manufacturer for repackaged product:					
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=""/>							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="10"/>					<input type="text" value="00355150427109"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text" value="120"/>					<input type="text" value="50355150427104"/>	
<input type="checkbox"/> Case	<input type="text" value="7200"/>					<input type="text" value="70355150427108"/>	
<input type="checkbox"/> Pallet	<input type="text" value=""/>					<input type="text" value=""/>	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		<input type="text" value="\$110.00"/>		Vendor #:		<input type="text" value=""/>	
Invoice Cost (WAC) (\$)		<input type="text" value=""/>		Whsl. Code #:		<input type="text" value=""/>	
As of date: <input type="text" value="5/19/2023"/>				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:		<input type="text" value="D.Venkata Surender Reddy"/>	