

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

Version 2021						Introduction [*]	Type: Ne	ew Item		Final Version			Date:	14.05	5.2023		
			PRODUCT INFORMAT	TION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*				
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):								Temperature Range Cold – between 2 and 8 C (36° – 46° F)								
Medical Device Class, if applica		, ,,	•						1								
DUNS:	968961354								"	Other Temperature Range I	Requirement						
Proprietary Name (If Applicable)	and Established N	Name: Diltiaz	zem Hydrochloride Injection 2	25 mg per 5 ml						(write in)							
Selling Unit NDC:	55150-0425-10		Unit of Use NDC:		55150-0425-01	UPC:	355150425105			Notes		DO NOT FF	REEZE				
UDI			CVX Code:			MVX Code:											
Description:	Diltiazem Hvdrod	chloride Injection 25 m	ng per 5 mL (5 mg/mL)(10 Vi	ials)					1	Is this product to be shipped	d to customers on	ice?		No			
•	,	•		,						Is this product to be shipped				No			
Active Ingredient(s):		Diltiazem Hydroch	loride						1			•			1		
									b. Contact for	temperature excursion qu	estions:						
URL for Additional Product Infor	mation:	eugiaus.com								Name:		Kevin Cagn					
Address:	279 Princeton-Hi	ghtstown Road				Address 2:				Number:	732.839.9400 ex 8009						
City:	East Windsor				State:	NJ	J Zip: 08520			Group E-mail:		kcagnetti@EugiaUS.com					
Key Contact:	200 200 7000				Email:	700 055 0440											
Phone Number:	888-238-7880				Fax: 732-355-9449				c. Special regi	ulations for product in any		No			-		
Product Therapeutic Classification	on:	Calcium ion influx	inhibitor							Special returns requirement	ts for this product?			No]		
															1		
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT	DESCRIPTION INF	ORMATION	d. Store produ	ict (unit of sale) upright?				No	1		
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	ale) from light?			No			
a legend device?		No	Is the Product	Neither		Size:	10 x 5 mL	Single-Dose Vi	e. Shelf life:					24	Months		
if yes, enter class #			Orphan Drug Status			0.20.				Initial shelf life at launch (if different):				Months		
a product kit?		No				Strength:	25 mg per	5 mL				ATION					
if yes, list NDCs of			FDA Approval Status				0-1-4:				ORDER INFORM	IATION					
component parts		NI-				Dosage For	m: Solution			Unit of Cala		What is the	NDC selling	a unit?			
reverse numbered? co-licensed?		No	Allergens Present							Unit of Sale Bottle		1 box of 10		y unit?			
latex-free?		No Yes	Allergens Present							x Box/Carton		-	g. 1 Box of 1	In Vials)			
preservative-free?		Yes				Product Sha	ape:			Ampule		(VVIIIC-III, C	.g. I box of I	io viais)			
correctional institution block?		No					Colorless			Glass		Minimum o	rder quantit	v?	Yes		
opioid?		No				Product Col	lor:			Tube				•			
Cannabinoid?		No	Country of Origin	India		Due divet les				Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	unit dose for					Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?		
hospital scanning?			Is this product covered u						Vial Powder Sql				Each				
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No					Vial Power Multi			Inner/Cartor	n/Pack			
]	Other: Write In		1	Case				
			FOR GENERIC DRUG PRO	DDUCTS													
					Aut	horized Generic	*If Authorized Ger			PH/	ARMACY ORDER	/ BILL UNIT					
I. Orange Book Rating:	AP						section fields are	not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	пасу:			
II. Generic Equivalent to What Br	and?:	Cardizem Injection	1							1 vial		x Each					
									(Write-in, e.g.	1 Vial)			Gram				
		DRUG SUPPL	Y CHAIN SECURITY ACT (I	DSCSA) INFO	RMATION								Milliliter				
Daniel and Book definition	*******************************		V	_	OL NI					ITEM	AND PACKING II	JEODMATIO	NI.				
Does supplier meet DSCSA defin		urer?	Yes	_	GLN:					IIEM	AND PACKING II	NFURMATIU	N				
Is product exempt from DSCSA?			No						-			22 F =					
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msn	•	Volume	Saleable #		
Other exemption - Write in:			Na		le	alaal oo ah da sa			Harry/Factor		Depth	Width	Height	(Cube)	Pieces		
Is product repackaged?	o ovolucius distal	hutor?	No No	_	If yes, was ori purchased dir				Item/Each:	0.383	5.12	2.05	1.97	20.677	10		
Is product sold by manufacturer's Has FDA granted waiver/exception			INU		•		for repackaged pro	oduct	Box/Carton/B	undle/							
If yes, attach documentation fro		products			1 TO VIGE SOUT	o manuracturer	ioi iepackageu pro	oduci	Inner Pack:	undo							
yes, attach documentation no	m i DA.								Case:								
		GTIN	N AND HIBCC PRODUCT IN	FORMATION					1	8.666	11.614	9.252	9.645	1036.382	200		
									Pallet:				40.50		10000 00		
Saleable Unit of Measure	:	Saleable Quantity	HIBCC		GTIN	I-14	Unit of Us	se GTIN-14		761.01	48	40	43.58	83673.60	16800.00		
x Item/Each		10			_	5150425105											
x Box/Carton/Bundle/Inner Pack										COST INFORMATION		\	WHOLESAL	ER USE ONL	Y:		
x Case		200				5150425100											
x Pallet	_	16800			7035	5150425104			Regular Cost			Vendor #:					
	_								Invoice Cost (WAC) (\$)	\$38.00	Whsl. Code					
	-											Fineline Co	de:				
	_						_		As of date:	5/19/2023							
<u> </u>			Au 1 (01===:::::		<u> </u>			ND DUCT: :=		4 O.N.O		1					
*Diagon provide a sure	£		Attach copy of SAFETY DAT	A SHEET (SD	S) or non hazard				PRODUCT PACK) Ve-1-1-0	man de D. L.	h.,		
*Please provide any additional in	tormation on pag	e 2.				See new p. 3 fo	r Designated Drop	Ship Only.		Signature:			venkata Sر.venkata Sر	urender Redd	y		



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

Version 2021						Introduction 1	Type: New Ite	em		Final Version			Date:	14.05	5.2023		
			PRODUCT INFORMAT	TION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*				
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/AN	,	16552				Temperature Range Cold – between 2 and 8 C (36° – 46° F)											
Medical Device Class, if applica			•										,				
DUNS:	968961354								' C	Other Temperature Range F	Requirement						
Proprietary Name (If Applicable)	and Established N	Name: Diltiaz	zem Hydrochloride Injection s	50 mg per 10 m	nĹ					(write in)							
Selling Unit NDC:	55150-0426-10		Unit of Use NDC:		55150-0426-01	1 UPC:	355150426102		N	lotes		DO NOT FR	REEZE				
UDI			CVX Code:			MVX Code:											
Description:	Diltiazem Hydrod	chloride Injection 50 m	ng per 10 mL (5 mg/mL)(10 v	√ials)					Is	s this product to be shipped	I to customers on i	ce?		No			
•	,	•		,						s this product to be shipped				No			
Active Ingredient(s):		Diltiazem Hydroch	loride									•			1		
									b. Contact for to	emperature excursion que	estions:						
URL for Additional Product Infor	mation:	eugiaus.com							N	lame:		Kevin Cagne					
Address:	279 Princeton-Hi	ghtstown Road				Address 2:				lumber:		732.839.9400 ex 8009					
City:	East Windsor				State:	NJ	Zip : 08520			Group E-mail:		kcagnetti@EugiaUS.com					
Key Contact:	222 222 =222				Email:										1		
Phone Number:	888-238-7880				Fax: 732-355-9449				' '	ations for product in any		No			-		
Product Therapeutic Classification	on:	Calcium ion influx	inhibitor						S	Special returns requirement	s for this product?			No	1		
															1		
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT	DESCRIPTION INFORM	IATION	d. Store produc	t (unit of sale) upright?				No	1		
The product is?			Is the Product	Direct-Ship	Only				P	Protect product (unit of sa	le) from light?			No			
a legend device?		No	Is the Product	Neither		Size:	10 x 10 mL Sing	gle-Dose V	e. Shelf life:					24	Months		
if yes, enter class #			Orphan Drug Status			0.20.			Ir	nitial shelf life at launch (i	if different):				Months		
a product kit?		No				Strength:	50 mg per 10 ml	L				ATION					
if yes, list NDCs of			FDA Approval Status				0-1-4:				ORDER INFORM	IATION					
component parts		NI-				Dosage Form	m: Solution			Init of Colo		What is the	NDC colling	a unit?			
reverse numbered? co-licensed?		No	Allergens Present							Jnit of Sale Bottle		1 box of 10		y unit?			
latex-free?		No Yes	Allergens Present						-	x Box/Carton		_	g. 1 Box of 1	In Vials)			
preservative-free?		Yes				Product Sha	ipe:			Ampule		(**************************************	.g. 1 Dox of	io viais)			
correctional institution block?		No					Colorless			Glass		Minimum o	rder quantit	v?	Yes		
opioid?		No				Product Col	or:			Tube			4	,			
Cannabinoid?		No	Country of Origin	India		Due divet les				Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	unit dose for					Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?		
hospital scanning?			Is this product covered u							Vial Powder Sql			Each				
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carton/Pack					
										Other: Write In		1	Case				
			FOR GENERIC DRUG PRO	DDUCTS													
					Aut	horized Generic	*If Authorized Generic,			PHA	RMACY ORDER	/ BILL UNIT					
I. Orange Book Rating:	AP						section fields are not ap	pplicable	Rec. sell unit to	customer?		Rx billing u	nit to pharn	пасу:			
II. Generic Equivalent to What Br	and?:	Cardizem Injection	1							1 Vial		x Each					
									(Write-in, e.g. 1	Vial)			Gram				
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION								Milliliter				
Daniel and Book definition			V	_	OL N.					ITEM	AND DACKING IN	IFORMATION	vi .				
Does supplier meet DSCSA defin		urer?	Yes No	_	GLN:					ITEM	AND PACKING IN	NFORMATIO	V				
Is product exempt from DSCSA?			INU														
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msn	•		Saleable #		
Other exemption - Write in:			NI-		16	inimal condition			Now /F : : 1	V 1 111	Depth	Width	Height	(Cube)	Pieces		
Is product repackaged?	o ovolustico dist	hutar2	No	_	If yes, was ori	iginal product rect from mfr?			Item/Each:	0.4962	5.31	2.17	2.36	27.194	10		
Is product sold by manufacturer's Has FDA granted waiver/exception			No		-		or repackaged product	•	Box/Carton/Bun	ndle/							
If yes, attach documentation fro	-	productr			Frovide Source	Le manulacturer t	or repackageu product		Inner Pack:	iuie/							
in yes, attach documentation no	mi i DA.								Case:								
		GTIN	N AND HIBCC PRODUCT IN	FORMATION					Cust.	12.901	14.567	12.008	6.299	1101.824	240		
									Pallet:				40.00	22.472.22	12222		
Saleable Unit of Measure	:	Saleable Quantity	HIBCC		GTIN	N-14	Unit of Use GT	ΓIN-14		729.69	48	40	42.80	82176.00	12960		
x Item/Each		10			_	5150426102											
Box/Carton/Bundle/Inner Pack										COST INFORMATION		\	WHOLESAL	ER USE ONL	Y:		
Case		240			5035	5150426107											
Pallet	_	12960			7035	5150426101			Regular Cost			Vendor #:					
	1								Invoice Cost (W	/AC) (\$)	\$68.80	Whsl. Code					
	4						-					Fineline Co	de:				
	4						-		As of date:	5/19/2023							
							1										
<u> </u>			Au 1 (21		20)					200 121222		<u> </u>					
*BL			Attach copy of SAFETY DAT	A SHEET (SD	os) or non hazard								21/				
*Please provide any additional in	tormation on pag	e 2.				See new p. 3 for	Designated Drop Ship	Only.	S	Signature:			venkata Sı.	urender Redd	y		



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

Version 2021						Introduction 1	Туре:	New Item		Final Version			Date:	14.05	.2023
			PRODUCT INFORMAT	ION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Eugia US LLC (f/k/a Auro	Medics Pharm	na LLC)			Applicat	tion:	ANDA	a. Temperatu	re – Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN	,		· · · · · · · · · · · · · · · · · · ·	21	6552					Temperature Range	Cold – between 2				
Medical Device Class, if applical			,							, ,					
DUNS:	968961354								'	Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a	and Established Name:	Diltiaze	em Hydrochloride Injection 1	25 mg per 25	mL					(write in)					
Selling Unit NDC:	55150-0427-10		Unit of Use NDC:		55150-0427-0		35515042	27109		Notes		DO NOT FR	EEZE		
UDI			CVX Code:			MVX Code:									
Description:	Diltiazem Hydrochloride II	jection 125 m	ng per 25 mL (5 mg/mL)(10	Vials)						Is this product to be shipped	to customers on id	ce?		No	1
										Is this product to be shipped	to customers on d	Iry ice?		No	
Active Ingredient(s):	Diltiaz	em Hydrochlo	ride												
									b. Contact for	r temperature excursion qu					
URL for Additional Product Inforr						A -1 -1 O -				Name:		Kevin Cagnetti 732.839.9400 ex 8009 kcagnetti@EugiaUS.com			
Address:	279 Princeton-Hightstown East Windsor	Road			State:	Address 2:	Zip: 0	8520		Number:					
City: Key Contact:	East Willusui				Email:	INJ	Zip. 0	0320		Group E-mail:		Kcagnetti	veuglaus.	<u>LOM</u>	
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special reg	ulations for product in any	states?			No	1
Product Therapeutic Classificatio		m ion influx in	hibitor			. 02 000 0 1 10			or openiar reg	Special returns requirement				No	
										opeoiai returns requirement	3 for this product:			140	
	ADDITIONAL P	RODUCT INF	ORMATION			PRODUCT	DESCRIPT	ION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	ala) from licht?			No	ĺ
a legend device?	No		Is the Product	Neither	City		10	x 25 mL Single-Dose V	e. Shelf life:	i rotest product (dilit of Sa	aie, iroin ligilt?			24	Months
if yes, enter class #	140		Orphan Drug Status	T Columbia		Size:		X 20 III2 Giligio Bood V		Initial shelf life at launch (if different):			21	Months
a product kit?	No						12	5 mg per 25 mL		(
if yes, list NDCs of	FDA Approval Status					Strength:					ORDER INFORM	ATION			
component parts						Dosage Form	m. So	lution							
reverse numbered?	No					Dosage 1 on				Unit of Sale		What is the		unit?	
co-licensed?	No		Allergens Present							Bottle		1 box of 10			
latex-free?	Yes					Product Sha	аре:			x Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?	Yes						Co	lorless		Ampule Glass		Minimum	rdor aucontit	a	Yes
opioid?	No No					Product Col	lor:	oloriess		Tube		Minimum o	ruer quantit	/	res
Cannabinoid?	No		Country of Origin	India						Vial Liquid Sgl					
If Unit Dose, is item bar coded to u			ocurry or origin	a.u		Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?			Is this product covered up	nder the					Vial Powder Sql			Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ГАА)?	No				Vial Power Multi			Inner/Carton/Pack			
										Other: Write In		1	Case		
		F	FOR GENERIC DRUG PRO	DDUCTS											
					Aut	horized Generic		ized Generic, other		PH/	ARMACY ORDER	BILL UNIT			
I. Orange Book Rating:	AP						section fie	elds are not applicable	Rec. sell unit	Rx billing unit to pharmacy:					
II. Generic Equivalent to What Bra	and?: Cardiz	em Injection								1 vial		x Each			
		IIO OLIBBI V	CHAIN OF CURITY ACT (2000 A) INIEO	DMATION				(Write-in, e.g.	1 Vial)			Gram		
	DF	UG SUPPLY	CHAIN SECURITY ACT (D	JSCSA) INFO	ZIVIA I ICINI								Milliliter		
Does supplier meet DSCSA defini				,	KWATION										
	ition of manufacturer?			7							AND PACKING IN	FORMATION	N		
Is product exempt from DSCSA?			Yes No		GLN:					ITEM	AND PACKING IN	FORMATION	N		
Is product exempt from DSCSA?			Yes		GLN:									Volume	Saleable #
If yes, select exemption:			Yes							ITEM Weight Lbs.	Dimensio	ons (US msn	nts.)		Saleable #
If yes, select exemption: Other exemption - Write in:			Yes		GLN:	iginal product			Item/Each:	Weight Lbs.	Dimensio Depth	ons (US msn Width	nts.) Height	(Cube)	Pieces
If yes, select exemption:			Yes No		GLN: GCP: If yes, was or	iginal product rect from mfr?			Item/Each:		Dimensio	ons (US msn	nts.)		
If yes, select exemption: Other exemption - Write in: Is product repackaged?	s exclusive distributor?	,	Yes No		GLN: GCP: If yes, was or purchased di		for repacka	aged product	Box/Carton/B	Weight Lbs. 1.2301	Dimensio Depth	ons (US msn Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor? on/exemption for product	,	Yes No		GLN: GCP: If yes, was or purchased di	rect from mfr?	for repacka	aged product	Box/Carton/B Inner Pack:	Weight Lbs. 1.2301	Dimensio Depth	ons (US msn Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distributor? on/exemption for product		Yes No No		GLN: GCP: If yes, was or purchased di	rect from mfr?	for repacka	aged product	Box/Carton/B	Weight Lbs. 1.2301	Dimensio Depth	ons (US msn Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distributor? on/exemption for product		Yes No		GLN: GCP: If yes, was or purchased di	rect from mfr?	for repacka	aged product	Box/Carton/B Inner Pack: Case:	Weight Lbs. 1.2301	Dimension Depth 6.69	ons (US msn Width 2.76	nts.) Height 3.15	(Cube) 58.163	Pieces 10
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	s exclusive distributor? on/exemption for product' om FDA.	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased did Provide source	rect from mfr? ce manufacturer f			Box/Carton/B Inner Pack:	Weight Lbs. 1.2301	Dimension Depth 6.69	ons (US msn Width 2.76	nts.) Height 3.15	(Cube) 58.163	Pieces 10
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	s exclusive distributor? on/exemption for product' om FDA. Saleable	GTIN A	Yes No No		GLN: GCP: If yes, was or purchased did Provide source	rect from mfr? ce manufacturer f		aged product Unit of Use GTIN-14	Box/Carton/B Inner Pack: Case:	Weight Lbs. 1.2301 Sundle/ 15.975	Dimension	2.76 9.646	3.15 8.268	(Cube) 58.163 1193.187	10 120
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure x Item/Each	s exclusive distributor? on/exemption for product' om FDA.	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased did Provide source	rect from mfr? ce manufacturer f			Box/Carton/B Inner Pack: Case:	Weight Lbs. 1.2301 Sundle/ 15.975	Dimension	9.646	8.268 46.34	(Cube) 58.163 1193.187	10 120 7200
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	s exclusive distributor? on/exemption for product' om FDA. Saleable	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased directly provide sources and the source of the so	rect from mfr? ce manufacturer f			Box/Carton/B Inner Pack: Case:	Weight Lbs. 1.2301 Sundle/ 15.975 991.51	Dimension	9.646	8.268 46.34	(Cube) 58.163 1193.187 88972.80	10 120 7200
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure x Item/Each Box/Carton/Bundle/Inner Pack	s exclusive distributor? on/exemption for product' om FDA. Saleable	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased directly provide source GTIN 0035	rect from mfr? ce manufacturer f			Box/Carton/B Inner Pack: Case:	Weight Lbs. 1.2301 Sundle/ 15.975 991.51 COST INFORMATION	Dimension Depth 6.69 14.961 48	9.646 40 Vendor #:	8.268 46.34	(Cube) 58.163 1193.187 88972.80	10 120 7200
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure x	s exclusive distributor? on/exemption for product' om FDA. Saleable	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased directly provide source GTIN 0035	N-14 55150427104			Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 1.2301 Sundle/ 15.975 991.51 COST INFORMATION	Dimension Depth 6.69 14.961 48	9.646 40 Vendor #: Whsl. Code	8.268 46.34 WHOLESAL	(Cube) 58.163 1193.187 88972.80	10 120 7200
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure x	s exclusive distributor? on/exemption for product' om FDA. Saleable	GTIN A	Yes No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased directly provide source GTIN 0035	N-14 55150427104			Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Weight Lbs. 1.2301 1.5.975 991.51 COST INFORMATION (WAC) (\$)	Dimension Depth 6.69 14.961 48	9.646 40 Vendor #:	8.268 46.34 WHOLESAL	(Cube) 58.163 1193.187 88972.80	10 120 7200
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