

		Intro	duction Type:	New Item		Fir	nal Version		Date:		
		PRODUCT INFORMATION			•		SPECIAL HAN	DLING AND ST	ORAGE REQUI	REMENTS*	
Company Name: Auro	oMedics Pharma LLC			Application: AND	A	a. Temperature	- Indicate the	USP temperat	ure range for th	nis product.	
Application Number for ND		206781				F	Freezer – betwe	een -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary Name:	DEXAMETHA	SONE SODIUM PHOSPHA	TE INJECTION I	JSP 4 mg per ml (SDV)	i		Cold – betweer	n 2 and 8 C (36°	– 46° F)		
	50-237-01		UPC:	355150237012				n 8 and 15 C (46	,		
CVX Code:			MVX Code:) and 25 C (68°	– 77° F)	
Description: DE>	XAMETHASONE SODIUM PHOS	PHATE INJECTION USP 4	ma per ml (SD)	/)			allows for excu	ursions between	15 and 30 C (59)° – 86° F)	
				,		V.	Avoid Excessiv	ve Heat – above	40 C (>104° F)		
Active ingredients:						VI.	. Other Temper (write in)	ature Range Re	quirement		1
URL for Additional Product Int	formation:					VII	I. No Requirem	ent			1
Address: 6 W	/heeling Road		Address 2:			b. Contact for t	emperature ex	cursion questi	ons:		
City: Day	/ton	State:	NJ	Zip: 08810		Name:					
Key Contact:		Email:				Number:					
Phone Number: 888	-238-7880	Fax:	732-355-9449	1		-		to customers or		No	_
	FOF	R GENERIC DRUG PRODUC	CTS			Is this produc	t to be shipped	to customers or	n dry ice?	No	-
I. Orange Book Rating: AP		II. Brand Name:									
III. Generic Equivalent for Bran	nd:					c. Special regu	lations for pro	duct in certain	states?	No	-
	DRUG SUPPLY CH	AIN SECURITY ACT (DSCS	SA) INFORMATI	ON		Special return	ns requirements	for this product	?	No	
Does supplier meet DSCSA de	efinition of manufacturer?	Yes	DUNS:	968961354							-
Is product exempt from DSCS	A? No					d. Store produ	ct (unit of sale	e) upright?		No	_
If yes, select exemption:						Protect proc	duct (unit of sa	ale) from light?		Yes	
Other exemption - Write in:						-		, -			-
Is product repackaged?	No	If Yes, was origina	al product purch	hased direct from mfr?		e. Shelf life:	24	Months			
Is product sold by manufactur		No		-			Initial shelf lif	e at launch (if o	different):		Months
Are any waivers granted for p	roduct ID/barcode?	No	If yes, attach	documentation from FDA							-
	ADDITIONAL	PRODUCT INFORMATION	l			:	ITEM AND	PACKING INFC	RMATION		
Is the Product Dire	ect Ship Item		ORDER INFOR	RMATION		Weight Lbs.	Dim	ensions (US ms	smts.)	Volume	# Pieces:
Legend Device?	No	Unit of Sale	What is the N	IDO estiliare control		weight Lps.	Depth	Height	147 141		
J			Timat le tile i	IDC selling unit?					Width:	(Cube)	# Fleces.
State Control?	No	Bottle	25 vial in one	-	Item:		•		width:	(Cube)	# Fleces.
State Control? ARCOS reportable?	No	Bottle x Box/Carton	25 vial in one	carton	Item:				Width:	(Cube)	# Fleces.
State Control? ARCOS reportable? Co-Licensed?	No No	Bottle x Box/Carton Ampule	25 vial in one	-	Box/	0.561 lbs	3.54 Inches	1.96 Inches	3.54Inches	(Cube)	25 Vials
State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	No	Bottle x Box/Carton Ampule Glass	25 vial in one (Write-in, e.g.	carton . 1 Box of 10 Vials)	Box/ Carton:	0.561 lbs	3.54 Inches	1.96 Inches	3.54Inches	(Cube)	25 Vials
State Control? ARCOS reportable? Co-Licensed?	No No	Bottle x Box/Carton Ampule	25 vial in one	carton . 1 Box of 10 Vials)	Box/					(Cube)	
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	No No	Bottle x Box/Carton Ampule Glass Tube	25 vial in one (Write-in, e.g. Minimum ord	carton . 1 Box of 10 Vials)	Box/ Carton: Case:	0.561 lbs 30.892 lbs	3.54 Inches 15.35 Inches	1.96 Inches 10.23 Inches	3.54Inches 11.81 Inches	(Cube)	25 Vials 48 cartons 12 x 4 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton:	0.561 lbs 30.892 lbs 867.113 lbs	3.54 Inches	1.96 Inches	3.54Inches	(Cube)	25 Vials 48 cartons
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48	arton I Box of 10 Vials) Ier quantity? Iany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	0.561 lbs 30.892 lbs 867.113 lbs Case:	3.54 Inches 15.35 Inches 48 Inches	1.96 Inches 10.23 Inches 38.90 Inches	3.54Inches 11.81 Inches	(Cube)	25 Vials 48 cartons 12 x 4 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item	No No No Agent?	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet:	0.561 lbs 30.892 lbs 867.113 lbs	3.54 Inches 15.35 Inches	1.96 Inches 10.23 Inches 38.90 Inches	3.54Inches 11.81 Inches	(Cube)	25 Vials 48 cartons 12 x 4 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to	No No No Agent?	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case:	3.54 Inches 15.35 Inches 48 Inches	1.96 Inches 10.23 Inches 38.90 Inches	3.54Inches 11.81 Inches 40 Inches	(Cube)	25 Vials 48 cartons 12 x 4 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning?	No No No Agent?	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER	25 vial in one (Write-in, e.g. Minimum ord If Yes, how n 1200 48 1	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton:	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR	3.54Inches 11.81 Inches 40 Inches		25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to	No No No Agent?	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	25 vial in one (Write-in, e.g. Minimum ord If Yes, how n 1200 48 1	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case:	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches	3.54Inches 11.81 Inches 40 Inches	Federal Exc	25 Vials 48 cartons 12 x 4 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered?	No No No Agent?	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1 / BILL UNIT ner?	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR	3.54Inches 11.81 Inches 40 Inches	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered?	No No No Agent? No o unit dose for	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1 / BILL UNIT ner?	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$)	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered?	No No No Agent? No o unit dose for	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1)	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1 / BILL UNIT ner?	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR Invoice Cos	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$)	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered? WHOLESALE Vendor #:	No No No Agent? No o unit dose for	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1 / BILL UNIT ner?	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost	3.54 Inches 15.35 Inches 48 Inches 355150237012	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR Invoice Cos	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$) 9.50	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered? WHOLESALE Vendor #: Whsl. Code #:	No No No Agent? No o unit dose for	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Each	25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 1200 48 1 / BILL UNIT ner?	carton . 1 Box of 10 Vials) ler quantity? Lach Inner/Carton/Pack Case Other Product Informati Size/Strength/Form: Product Shape: Product Color:	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost	3.54 Inches 15.35 Inches 48 Inches 355150237012 Per Unit of (\$)	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR Invoice Cos	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$)	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered? WHOLESALE Vendor #: Whsl. Code #:	No No No No Agent? No cunit dose for CR USE ONLY:	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	25 vial in one ((Write-in, e.g. Minimum ord 1200 48 1 / BILL UNIT her?	carton . 1 Box of 10 Vials) ler quantity?	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost Sale	3.54 Inches 15.35 Inches 48 Inches 355150237012 Per Unit of (\$)	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR Invoice Cos \$19 As of date:	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$) 9.50	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Is Item If Unit Dose, is item bar coded to hospital scanning? Is it reverse numbered? WHOLESALE Vendor #: Whsl. Code #:	No No No Agent? No cunit dose for CR USE ONLY: Attach copy of S	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	25 vial in one (Write-in, e.g. Minimum ord 1200 48 1 / BILL UNIT her?	carton . 1 Box of 10 Vials) ler quantity? Lany of which package type? Each Inner/Carton/Pack Case Other Product Informati Size/Strength/Form: Product Shape: Product Color:	Box/ Carton: Case: Pallet: UPC:	0.561 lbs 30.892 lbs 867.113 lbs Case: Carton: Regular Cost Sale	3.54 Inches 15.35 Inches 48 Inches 355150237012 Per Unit of (\$)	1.96 Inches 10.23 Inches 38.90 Inches 2 COST INFOR Invoice Cos \$19 As of date:	3.54Inches 11.81 Inches 40 Inches RMATION st (WAC) (\$) 9.50	Federal Exc	25 Vials 48 cartons 12 x 4 Inner 27 Shippers



	esignated Drop Ship Only Products, Please Use Page 3
	IAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? No d. Does this product require special clean-up instructions? No	Hazardous Waste Identification EPA Hazardous Waste Code:
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	_
Is this product regulated for shipment by the DOT? No Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit?	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?
(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#	ADDITIONAL PRODUCT INFORMATION - Serialization Level How? GTIN-14 Serialized? Item 2D Linear RFID 10355150237019 If not, when? Box/Carton 2D Linear RFID 00355150237012 Items aggregated to case? Case 2D Linear RFID 50355150237017 Pallet 2D Linear RFID 70355150237011
	REMS or REGISTRY RESTRICTIONS
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
Listed Chemical (List I or II) (Indicate or Write-in below): Ephedrine Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%) Other:	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?
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	



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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:	
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Sujo di vicei oranigiri le dialable. Tuesday Wednesday Thursday Friday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone: Phone #: Fax: EDI: Overnight Fees apply: Image: Constraint of the state of the s
REMS or Registry Restrictions	Return Instructions
REMS: Phone: Phone: Supplier Manages REMS registry exclusively: Phone: Phone: Wholesale distributor support: Provider Name: Phone: Site Enrollment Number assigned by Supplier: DEA #: Phone: PCPDP #: PCPDP #: Phone:	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?
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	



© August 2014			Intro	duction Type:				Fir	nal Version		Date:		
		PR	ODUCT INFORMATION						SPECIAL HAN	IDLING AND ST	ORAGE REQU	REMENTS*	
Company Name:	AuroMedics Pharma LL	C			Application:	ANDA	4	a. Temperature	- Indicate the	e USP temperat	ure range for th	nis product.	
Application Number f	or NDA/ANDA/BLA, Med	Device:	206781					I. F	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary	Name:	DEXAMETHASO	NE SODIUM PHOSPHA	TE INJECTION	USP 20 mg/5 mL (4 mg/mL) (M	MDV)		II.	Cold – betweer	n 2 and 8 C (36°	– 46° F)		
NDC:	55150-238-05			UPC:	355150238057				Cool - betwee	en 8 and 15 C (4	6° – 59° F)		
CVX Code:				MVX Code:				x IV.	. Controlled Ro	om – between 2	0 and 25 C (68°	– 77° F)	
Description:	DEXAMETHASONE SODIUM PHOSPHATE INJECTION USP 20 mg/5 mL (4 mg/mL) (MDV)										15 and 30 C (59	° – 86° F)	
Active ingredients:	its:									ve Heat – above rature Range Re	, ,		7
URL for Additional Prod	luct Information:							VI	I. No Requirem	ent			
Address:	6 Wheeling Road			Address 2:				b. Contact for t	emperature e	xcursion quest	ions:		
City:	Dayton		State:	NJ	Zip: 08810			Name:					
Key Contact:			Email:					Number:					
Phone Number:	888-238-7880		Fax:	732-355-9449	9					to customers or		No	_
		FOR G	ENERIC DRUG PRODUC	стѕ				Is this produc	t to be shipped	to customers or	n dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:										
III. Generic Equivalent fo	or Brand:							c. Special regu	lations for pro	oduct in certain	states?	No	
	DRUG	SUPPLY CHAIN	N SECURITY ACT (DSCS	SA) INFORMAT	ION		-	Special return	ns requirements	s for this product	1?	No	_
Doos supplier most DSC	CSA definition of manufa	oturor?	Yes	DUNS:	968961354								-
Is product exempt from		No	1es	DONO.	300301334			d. Store produ	ict (unit of sale	e) upright?		No	
								•	•	, , ,		Yes	-
If yes, select exemption Other exemption - Wr								Protect prot	auct (unit of sa	ale) from light?		res	-
Is product repackaged?		No	If Yes, was origina	al product purc	hased direct from mfr?			e. Shelf life:	24	Months			
Is product sold by manu	Ifacturer's exclusive dist	ributor?	No						Initial chalf life	fe at launch (if	different).		
is product sold by mana		inductor :	INU						initial Shell in	ie al iaurich (ir (unierenty.		Months
	d for product ID/barcode		No	If yes, attach	documentation from FDA				initial Shell in	ie at laulieli (ii i	umerentj.		Months
	d for product ID/barcode	?			documentation from FDA					PACKING INFO			Months
	d for product ID/barcode	?	No						ITEM AND	•	ORMATION	Volume	-1
Are any waivers granted	l for product ID/barcode	? ADDITIONAL PF	No	I ORDER INFOR				Weight Lbs.	ITEM AND	PACKING INFO	ORMATION	Volume (Cube)	# Pieces:
Are any waivers granted Is the Product Legend Device? State Control?	l for product ID/barcode	? ADDITIONAL PF No No	No RODUCT INFORMATION Unit of Sale Bottle	I ORDER INFOR	RMATION NDC selling unit?		Item:		ITEM AND Dim	PACKING INFO	DRMATION smts.)		-1
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	l for product ID/barcode	? ADDITIONAL PF No No No	No RODUCT INFORMATION Unit of Sale Bottle x Box/Carton	ORDER INFOR What is the N 25 vial in one	RMATION NDC selling unit? carton		Item:		ITEM AND Dim	PACKING INFO	DRMATION smts.)		-1
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	l for product ID/barcode	? ADDITIONAL PF No No No	No RODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule	ORDER INFOR What is the N 25 vial in one	RMATION NDC selling unit?		Box/		ITEM AND Dim	PACKING INFO	DRMATION smts.)		-1
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	l for product ID/barcode	? ADDITIONAL PF No No No	No RODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass	ORDER INFOR What is the N 25 vial in one (Write-in, e.g	RMATION NDC selling unit? carton j. 1 Box of 10 Vials)		Box/ Carton:	Weight Lbs.	ITEM AND Dim Depth 5.31 Inches	PACKING INFO ensions (US m Height 1.96 Inches	DRMATION smts.) Width: 5.31 Inches		# Pieces:
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	I for product ID/barcode Direct Ship Item - - - -	? ADDITIONAL PF No No No	No RODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule	ORDER INFOR What is the N 25 vial in one	RMATION NDC selling unit? carton j. 1 Box of 10 Vials)	S	Box/	Weight Lbs.	ITEM AND Dim Depth	PACKING INFO ensions (US m Height	DRMATION smts.) Width:		# Pieces:
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narco Controlled Substance C	I for product ID/barcode Direct Ship Item	? ADDITIONAL PF No No No No	No RODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord	RMATION NDC selling unit? carton j. 1 Box of 10 Vials) der quantity? <u>Ye</u> many of which package type?		Box/ Carton:	Weight Lbs.	ITEM AND Dim Depth 5.31 Inches	PACKING INFO ensions (US m Height 1.96 Inches	DRMATION smts.) Width: 5.31 Inches		# Pieces:
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol	I for product ID/barcode Direct Ship Item	? ADDITIONAL PF No No No	No RODUCT INFORMATION Unit of Sale Bottle Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFO What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400	RMATION NDC selling unit? carton j. 1 Box of 10 Vials) der quantity? Ye nany of which package type? Each		Box/ Carton: Case: Pallet:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs	ITEM AND Dim Depth 5.31 Inches 11.22 Inches	PACKING INF(ensions (US m Height 1.96 Inches 8.85 Inches	DRMATION smts.) Width: 5.31 Inches 11.22 Inches		# Pieces: 25 Vials 16 cartons
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narco Controlled Substance C	I for product ID/barcode Direct Ship Item	? ADDITIONAL PF No No No No	No RODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord	RMATION NDC selling unit? carton j. 1 Box of 10 Vials) der quantity? <u>Ye</u> many of which package type?		Box/ Carton: Case:	Weight Lbs. 1.03 lbs 8.21 lbs	ITEM AND Dim Depth 5.31 Inches 11.22 Inches	PACKING INF(ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches	DRMATION smts.) Width: 5.31 Inches 11.22 Inches		# Pieces: 25 Vials 16 cartons
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoi Controlled Substance C Hazardous Material/Cyto	d for product ID/barcode' Direct Ship Item tic) oode:	? ADDITIONAL PF No No No No	No No RODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Vial Power Multi	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16	RMATION NDC selling unit? carton J. 1 Box of 10 Vials) der quantity? Ye nany of which package type? Each Inner/Carton/Pack		Box/ Carton: Case: Pallet:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case:	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches	PACKING INF(ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches	DRMATION smts.) Width: 5.31 Inches 11.22 Inches		# Pieces: 25 Vials 16 cartons
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoi Controlled Substance C Hazardous Material/Cyto	d for product ID/barcode' Direct Ship Item tic) oode:	? ADDITIONAL PF No No No No	No No RODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Vial Power Multi	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1	RMATION NDC selling unit? carton J. 1 Box of 10 Vials) der quantity? Ye nany of which package type? Each Inner/Carton/Pack	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case:	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches	PACKING INF(ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches		# Pieces: 25 Vials 16 cartons
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoi Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	d for product ID/barcode Direct Ship Item 	? ADDITIONAL PF No	No CDUCT INFORMATION CDUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 1	RMATION NDC selling unit? carton J. 1 Box of 10 Vials) der quantity? Ye many of which package type? Each Inner/Carton/Pack Case	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case:	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057	PACKING INFO	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches	(Cube)	# Pieces: 25 Vials 16 cartons
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance C Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	d for product ID/barcode Direct Ship Item 	? ADDITIONAL PF No	No RODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 1	RMATION NDC selling unit? carton 1. 1 Box of 10 Vials) der quantity? Ye many of which package type? Each Inner/Carton/Pack Case Other Product Infe	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton:	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057	PACKING INFO	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoid Controlled Substance Co- Hazardous Material/Cyton Is Item If Unit Dose, is item bar co- hospital scanning? Is it reverse numbered?	d for product ID/barcode Direct Ship Item 	? ADDITIONAL PF No	No RODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how m 400 16 1	RMATION NDC selling unit? carton 1. 1 Box of 10 Vials) der quantity? Ye many of which package type? Each Inner/Carton/Pack Case Other Product Infe	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton: Regular Cost	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057	PACKING INFO ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches 7 COST INFO Invoice Cos	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers cise Tax Per
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoid Controlled Substance Co- Hazardous Material/Cyton Is Item If Unit Dose, is item bar co- hospital scanning? Is it reverse numbered?	d for product ID/barcode' Direct Ship Item tic) ode: otoxic Agent? oded to unit dose for	? ADDITIONAL PF No No No No No No No No	No CODUCT INFORMATION CODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In CODUCT Vite In CODUCT Vite CODUCT Rec. sell unit to custom	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 / BILL UNIT ner? I Vial)	RMATION NDC selling unit? carton J. 1 Box of 10 Vials) der quantity? Ye many of which package type? Each Inner/Carton/Pack Case Other Product Inf Size/Strength/Form:	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton: Regular Cost	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057	PACKING INFO ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches 7 COST INFO Invoice Cos	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers cise Tax Per
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Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance C Hazardous Material/Cyto Is item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #:	d for product ID/barcode' Direct Ship Item tic) ode: otoxic Agent? oded to unit dose for	? ADDITIONAL PF No No No No No No No No	No CODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. 1 Rx billing unit to pharm Each Gram	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 / BILL UNIT ner? I Vial)	RMATION NDC selling unit? carton U. 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product Inf Size/Strength/Form: Product Shape:	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton: Regular Cost	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057 Per Unit of (\$)	PACKING INFO ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches 7 COST INFO Invoice Cos	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches RMATION st (WAC) (\$) 5.00	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers cise Tax Per
Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol Controlled Substance C Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	d for product ID/barcode' Direct Ship Item tic) ode: otoxic Agent? oded to unit dose for	? ADDITIONAL PF No No No No No No No No	No CODUCT INFORMATION CUnit of Sale Bottle Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Multi Vial Power Nulti Other: Write In CHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. 1 Rx billing unit to pharm Each	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 / BILL UNIT ner? I Vial)	RMATION NDC selling unit? carton I. 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product Infe Size/Strength/Form: Product Shape: Product Color:	,	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton: Regular Cost	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 355150238057 Per Unit of (\$)	PACKING INFO ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches 7 COST INFO Invoice Cos	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers cise Tax Per
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Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol Controlled Substance Ci Hazardous Material/Cyto Is Item If Unit Dose, is item bar or hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #: Fineline Code:	d for product ID/barcode' Direct Ship Item tic) ode: Solution Agent? SALER USE ONLY:	? ADDITIONAL PF No No No No No No ach copy of SAF	No CODUCT INFORMATION Unit of Sale Bottle Bottle Sox/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	ORDER INFOR What is the N 25 vial in one (Write-in, e.g Minimum ord If Yes, how n 400 16 1 Vial) Ner? Vial) Nacy: () or non hazard	RMATION NDC selling unit? carton i. 1 Box of 10 Vials) der quantity? Ye nany of which package type? Each Inner/Carton/Pack Case Other Product Inf Size/Strength/Form: Product Shape: Product Color: Product Imprint:	ormatio	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 1.03 lbs 8.21 lbs 901.56 lbs Case: Carton: Regular Cost Sale	ITEM AND Dim Depth 5.31 Inches 11.22 Inches 48 Inches 3555150238057 Per Unit of (\$)	PACKING INFO ensions (US m Height 1.96 Inches 8.85 Inches 44.61 Inches 7 COST INFO Invoice Cos \$20 As of date:	DRMATION smts.) Width: 5.31 Inches 11.22 Inches 40 Inches RMATION st (WAC) (\$) 5.00	(Cube)	# Pieces: 25 Vials 16 cartons 48 Shippers



	ignated Drop Ship Only Products, Please Use Page 3
	L HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.)	Hazardous Waste Identification EPA Hazardous Waste Code:
e. Does the product contain DEHP? No	
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
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#	Level How? GTIN-14 Serialized? Item 2D Linear RFID 10355150238054 If not, when? Box/Carton 2D Linear RFID 00355150238057 Items aggregated to case? Case 2D Linear RFID 50355150238052 Pallet 2D Linear RFID 70355150238056
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
Listed Chemical (List I or II) (Indicate or Write-in below): Ephedrine Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%) Other:	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?
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	



		Intro	duction Type:	New Item		Fir	nal Version		Date:		
	PF	RODUCT INFORMATION			<u> </u>		SPECIAL HAN	IDLING AND ST	ORAGE REQU	REMENTS*	
Company Name: AuroMedics Pharma				Application: ANI	DA	a. Temperature	- Indicate the	USP temperat	ure range for th	is product.	
Application Number for NDA/ANDA/BLA, M		206781					Freezer – betwe	een -25 and -10	C (-13° – 14° F)		
Rx Product/Proprietary Name:	DEXAMETHAS	ONE SODIUM PHOSPHA	TE INJECTION I	USP 120 mg/30 mL (4 mg/mL) (MD\	Ŋ		Cold – betweer	n 2 and 8 C (36°	– 46° F)		
NDC: 55150-239-30			UPC:	355150239306	/			n 8 and 15 C (4	,		
CVX Code:			MVX Code:	-					0 and 25 C (68°	– 77° F)	
Description: DEXAMETHASONE	SODIUM PHOSPH	HATE INJECTION USP 12	20 ma/30 ml (4 r	mg/mL) (MDV)			allows for excu	ursions between	15 and 30 C (59	° – 86° F)	
			10 mg/00 m2 (1			V.	Avoid Excessiv	ve Heat – above	40 C (>104° F)		
Active ingredients:						VI	. Other Temper (write in)	ature Range Re	quirement		1
URL for Additional Product Information:						VI	I. No Requirem	ent			1
Address: 6 Wheeling Road			Address 2:			b. Contact for t	emperature ex	xcursion quest	ions:		
City: Dayton		State:	NJ	Zip: 08810		Name:					
Key Contact:		Email:				Number:					
Phone Number: 888-238-7880		Fax:	732-355-9449)				to customers or		No	_
	FOR G	SENERIC DRUG PRODUC	CTS			Is this produc	t to be shipped	to customers or	n dry ice?	No	-
I. Orange Book Rating: AP		II. Brand Name:									
III. Generic Equivalent for Brand:		•	•			c. Special regu	lations for pro	duct in certain	states?	No	
DR	UG SUPPLY CHAI	N SECURITY ACT (DSCS	SA) INFORMATI	ION		Special return	ns requirements	s for this product	?	No	-
Does supplier meet DSCSA definition of man	ufacturar?	Yes	DUNS:	968961354							-
Is product exempt from DSCSA?	No	165	Donto.	300301304		d. Store produ	ict (unit of sale	a) upright?		No	
		-				-	•	,			-
If yes, select exemption: Other exemption - Write in:						Protect proc	duct (unit of sa	ale) from light?		Yes	-
Is product repackaged?	No	If Yes, was origina	al product purch	hased direct from mfr?		e. Shelf life:	24	Months			_
Is product sold by manufacturer's exclusive of		No					Initial shelf lif	e at launch (if	different):		Months
Are any waivers granted for product ID/barco	ode?	No	If yes, attach	documentation from FDA							
	ADDITIONAL P	RODUCT INFORMATION					ITEM AND	PACKING INFO	ORMATION		
Is the Product Direct Ship Item											
			ORDER INFOR	RMATION		Weight Lbo	Dime	ensions (US m	smts.)	Volume	# Diagoni
Legend Device?	No	Unit of Sale	What is the N	IDC selling unit?		Weight Lbs.	Dime Depth	ensions (US m Height	smts.) Width:	Volume (Cube)	# Pieces:
State Control?	No	Bottle		IDC selling unit?	Item:	Weight Lbs.		•	,		# Pieces:
State Control? ARCOS reportable?	No No	Bottle x Box/Carton	What is the N 25 vial in one	IDC selling unit? carton	Item:	Weight Lbs.		•	,		# Pieces:
State Control? ARCOS reportable? Co-Licensed?	No No No	Bottle x Box/Carton Ampule	What is the N 25 vial in one	IDC selling unit?	Box/	Weight Lbs.		•	,		# Pieces: 25 Vials
State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	No No	Bottle x Box/Carton Ampule Glass	What is the N 25 vial in one (Write-in, e.g.	IDC selling unit? carton . 1 Box of 10 Vials)	Box/ Carton:	3.44 lbs	Depth 6.69 Inches	Height 3.14 Inches	Width: 6.69 Inches		25 Vials
State Control? ARCOS reportable? Co-Licensed?	No No No	Bottle x Box/Carton Ampule	What is the N 25 vial in one	IDC selling unit? carton . 1 Box of 10 Vials)	Box/		Depth	Height	Width:		
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	No No No	Bottle x Box/Carton Ampule Glass Tube	What is the N 25 vial in one (Write-in, e.g. Minimum ord	IDC selling unit? carton . 1 Box of 10 Vials)	Box/ Carton: Case:	3.44 lbs 16.62 lbs	Depth 6.69 Inches 14.56 Inches	Height 3.14 Inches 4.33 Inches	Width: 6.69 Inches 14.56 Inches		25 Vials 4 Carton 2 x 2 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic)	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each	Box/ Carton:	3.44 lbs 16.62 lbs 830.87 lbs	Depth 6.69 Inches	Height 3.14 Inches	Width: 6.69 Inches		25 Vials 4 Carton
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent?	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	3.44 lbs 16.62 lbs 830.87 lbs Case:	Depth 6.69 Inches 14.56 Inches 48 Inches	Height 3.14 Inches 4.33 Inches 46.18 Inches	Width: 6.69 Inches 14.56 Inches		25 Vials 4 Carton 2 x 2 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each	Box/ Carton: Case: Pallet:	3.44 lbs 16.62 lbs 830.87 lbs	Depth 6.69 Inches 14.56 Inches	Height 3.14 Inches 4.33 Inches 46.18 Inches	Width: 6.69 Inches 14.56 Inches		25 Vials 4 Carton 2 x 2 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1	ADC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case:	Depth 6.69 Inches 14.56 Inches 48 Inches	Height 3.14 Inches 4.33 Inches 46.18 Inches	Width: 6.69 Inches 14.56 Inches 40 Inches		25 Vials 4 Carton 2 x 2 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning?	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton:	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches	Width: 6.69 Inches 14.56 Inches 40 Inches	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1	ADC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case:	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches	Width: 6.69 Inches 14.56 Inches 40 Inches	(Cube)	25 Vials 4 Carton 2 x 2 Inner
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning?	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	What is the N 25 vial in one of (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 / BILL UNIT ner?	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches 5 COST INFO	Width: 6.69 Inches 14.56 Inches 40 Inches	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial)	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes hany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cost	Width: 6.69 Inches 14.56 Inches 40 Inches	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? WHOLESALER USE ONLY:	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1)	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial)	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes hany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: Product Shape:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cost	Width: 6.69 Inches 14.56 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? WHOLESALER USE ONLY: Vendor #:	No No No	Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial)	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes hany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: Product Shape:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cos \$24	Width: 6.69 Inches 14.56 Inches 40 Inches 8 40 Inches 8 2 2	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? WHOLESALER USE ONLY: Vendor #: Whsl. Code #:	No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial)	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: Product Shape: Product Color:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cost	Width: 6.69 Inches 14.56 Inches 40 Inches RMATION st (WAC) (\$)	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? WHOLESALER USE ONLY: Vendor #: Whsl. Code #: Fineline Code:	No No No No No	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial) Nacy:	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes hany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: Product Shape: Product Color: Product Imprint:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost Sale	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306 Per Unit of (\$)	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cos \$24 As of date:	Width: 6.69 Inches 14.56 Inches 40 Inches 8 40 Inches 8 2 2	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers
State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? WHOLESALER USE ONLY: Vendor #: Whsl. Code #: Fineline Code:	No No No No No Attach copy of SAF	Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custom (Write-in, e.g. 1 Rx billing unit to pharm Each Gram Milliliter	What is the N 25 vial in one (Write-in, e.g. Minimum ord If Yes, how m 100 4 1 Vial) hacy:	IDC selling unit? carton . 1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: Product Shape: Product Color:	Box/ Carton: Case: Pallet: UPC:	3.44 lbs 16.62 lbs 830.87 lbs Case: Carton: Regular Cost Sale	Depth 6.69 Inches 14.56 Inches 48 Inches 355150239306 Per Unit of (\$)	Height 3.14 Inches 4.33 Inches 46.18 Inches COST INFO Invoice Cos \$24 As of date:	Width: 6.69 Inches 14.56 Inches 40 Inches 8 40 Inches 8 2 2	(Cube)	25 Vials 4 Carton 2 x 2 Inner 48 Shippers



	esignated Drop Ship Only Products, Please Use Page 3
	IAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? d. Does this product require special clean-up instructions? No	Hazardous Waste Identification EPA Hazardous Waste Code:
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	_
Is this product regulated for shipment by the DOT? No Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
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#	Level How? GTIN-14 Serialized? Item 2D Linear RFID 10355150239303 If not, when? Box/Carton 2D Linear RFID 00355150239306 Items aggregated to case? Case 2D Linear RFID 50355150239301 Pallet 2D Linear RFID 70355150239305
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
Listed Chemical (List I or II) (Indicate or Write-in below): Ephedrine Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%) Other:	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?
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:
Restricted to recar praimacy only. Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	



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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:	
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Sujo di vicei oranigiri le dialable. Tuesday Wednesday Thursday Friday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone: Phone #: Fax: EDI: Overnight Fees apply: Image: Comparison of the state of the s
REMS or Registry Restrictions	Return Instructions
REMS: Phone: Phone: Supplier Manages REMS registry exclusively: Phone: Phone: Wholesale distributor support: Provider Name: Phone: Site Enrollment Number assigned by Supplier: DEA #: Phone: PCPDP #: PCPDP #: Phone:	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?
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	



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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only Phone No.:	
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:	
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday
Comments:	Suge of week oronnight is available. Tuesday Wednesday Thursday Friday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone: Phone #: Fax: EDI: Overnight Fees apply: Image: Comparison of the state of the s
REMS or Registry Restrictions	Return Instructions
REMS: Phone: Phone: Supplier Manages REMS registry exclusively: Phone: Phone: Wholesale distributor support: Provider Name: Phone: Site Enrollment Number assigned by Supplier: DEA #: Phone: PCPDP #: PCPDP #: Phone:	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?
Comments:	
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date:	



						Introduct	ion Type:	New Item]	Final Version			Date:	7/10/	2020
			PRODUCT IN	FORMATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	AuroMedics Pharma	LLC					Application:	ANDA	a. Temperature – Indi	cate the USP temper	rature range f	or this produ	ict.		
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med de	avice):	21	0967					ature Range	•			en 20 and 25	C (68° – 77° F
DUNS:	968961354								Other T	emperature Range Re	equirement				
Proprietary Name (If Applical	ble) and Established	Name: Dex	xamethasone Sodium Phe	osphate Injection, US	SP 100 mg/10mL	. (10mg/mL) MD	V (10 Vials)			rite in)		Store at 20°	to 25°C (68°	to 77°F) [see	
Selling Unit NDC:	55150-305-10		Individual Uni	t NDC:	55150-305-01	UF		05100							
UDI			CVX Code:			MVX Cod	e:		Is this p	roduct to be shipped t	to customers	on ice?		No	
Description:	Dexamethasone Sod	lium Phosphate Injec	ction, USP 100 mg/10mL	(10mg/mL) MDV (10	Vials)				Is this p	roduct to be shipped t	to customers	on dry ice?		No	
		Dexamethasone S	De d'une Die en die de												
Active Ingredient(s):		Dexamethasone 5	odium Priosphate						b. Contact for temperative Name:	ature excursion ques	stions:	Steve Lucas			
URL for Additional Product I	Information:								Numbe	r:		732-823-412	22		
Address:	279 Princeton-Hights	town Road				Address 2:			Group	E-mail:		slucas@aur	obindousa.co	m	
City:	East Windsor				State:	NJ	Zip:	08520	41 .						
Key Contact:	888-238-7880				Email: Fax:	732-355-9449			c. Special regulations					No	
Phone Number: Product Therapeutic Classifi					Fax:	732-300-9448	,		Special	returns requirements	for this produ	Ct?		NO	
Product Therapeutic Classin	ication:								d Store product (unit	of colo) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION			P	RODUCT DES	CRIPTION INFO	ORMATION	d. Store product (unit	product (unit of sale	a) from light?			No No	
Is the Product									e. Shelf life:	product (ant or call	o, nom nghti			18	Months
a legend device?		No								helf life at launch (if	different).			10	Months
reverse numbered?		No	<u> </u>		Size:	10 m	l x 10 vials			ine at launen (il	amorency.				lionuis
co-licensed?		No			Strength:	100 r	ng/10ml (10mg	/mL) MDV (10 Vials)		C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only			Strength.	1001	ng/Tome (Tomg								
Is the Product		Neither			Dosage Form:	LIQU	ID		Unit of	-		What is the		unit?	
									x	Bottle Box/Carton		55150-305-1 (Write-in, e.		0 \/iele)	
If Unit Dose, is item bar code	ed to unit dose for hosp	bital scanning?								Ampule		(write-iii, e.	9. I BUX UI I	0 viais)	
If Unit Dose NDC, indicate N	IDC here:				Product Shape	e: Vial F	Pack			Glass		Minimum o	der quantity	/?	Yes
					Product Color					Tube					
Country of Origin		India				·				Vial Liquid Sgl					
Is this product covered under	r the Trade Agreement	s Act (TAA)? No			Product Imprin	nt:				Vial Liquid Multi Vial Powder Sgl			many of wh Each	ich package t	ype?
		110	—							Vial Power Multi			Inner/Cartor	/Pack	
				L						Other: Write In			Case	, and a	
			FOR GENERIC D	RUG PRODUCTS											
					Autho	orized Generic		ized Generic, other section not applicable			RMACY ORDE				
I. Orange Book Rating: II. Generic Equivalent to Wha	AP	Hexadrol Injection					noido di o	not approable	Rec. sell unit to custo 1 box of		-	Rx billing u	nit to pharm Each	acy:	
II. Generic Equivalent to what	at brand ?:	nexadior injection							(Write-in, e.g. 1 Vial)	TO VIAIS		X	Gram		
		DRUG S	UPPLY CHAIN SECURIT	Y ACT (DSCSA) IN	FORMATION				(white in, e.g. 1 vital)				Milliliter		
									-						
Does supplier meet DSCSA of Is product exempt from DSC		turer?	Yes No	G	LN:					ITEM A	ND PACKING	INFORMATI	ON		
If yes, select exemption:											Dime	nsions (US m	ismts.)	Volume	
Other exemption - Write in:	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No		Yes, was origina	al product purc	hased direct		Item:	0.4774	5.31	2.36	2.17	27.193572	10 Vials
Is product sold by manufactu			No		om mfr?										
Has FDA granted waiver/exc	ception/exemption for	product?	No	If :	yes, attach docu	umentation from	n FDA.		Box/Carton/Bundle/ Inner Pack:	3.0643	13.82	2.99	5.75	237.60035	60 Vials
			GTIN PRODUCT	INFORMATION					Case:		-				
			,	Saleable						13.812	14.763	7.323	12.205	1319.47583	240 Vials
			Level	Unit			Quantity	GTIN-14	Pallet:	903.211	48	56.5	40	108480	15120 Vials
Serialized?	Yes		x Item		x 2D	Linear	10	00355150305100				00.0			10120 11010
If not, when?			x Box/Carton/Bundle/Inne	r Pack X	x 2D x 2D	Linear	60 240	30355150305101 50355150305105	UPC:	Case:					
Items aggregated?			x Case x Pallet		x 2D x 2D	Linear	15120	70355150305105	└────	Carton:					
					2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	Y:
					2D	Linear									
					2D	Linear			Regular Cost			Vendor #:			
					2D	Linear			Invoice Cost (WAC) (\$		\$95.00	Whsl. Code			
									Federal Excise Tax Pe As of date:	er Unit of Sale	1	Fineline Co	ue:		
									no or uale.						
			Attach copy of SAF	TY DATA SHEET (S	SDS) or non haza	ard letter, PACK	AGE INSERT. I	ABEL AND PHOTO OF PR	ODUCT PACKAGING and E	ARCODE.		•			
*Please provide any addition	nal information on pag	ge 2.		(,			d Drop Ship Only.	Signatu				Muramredd	y penchalaiah	



	nated Drop Ship Only Products, Please Use Page 3
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	000 11
a. Cytotoxic? No	SDS Hazard Classification
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive
Is the product a CA Prop 65 reproductive toxicant? No	Inorganic Oxidizer
Does the product label bear a CA Prop 65 warning? No	Steroid/Androgen Contact Hazard
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No
e. Does the product contain DEHP? No	If yes, indicate which:
Is this product regulated for shipment by DOT or IATA?	
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	
b. Proper Shipping Name	Hazardous Waste Identification
c. DOT Hazard Class	EPA Hazardous Waste Code:
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product? No
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
	WEDSITE ONL.
Is this a reportable quantity?	
RQ Threshold:	Comments / Details: (For example, iPledge program?)
Is this a marine pollutant?	
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
(if yes, identify method below)	REMS: No
Limited Quantity	REMS Program Manager Name: Phone:
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively:
Small Quantity (49 CFR 173.4)	Wholesale distributor support:
Special Permit; DOT-SP	Provider Name:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:
SP#	by Supplier: PCPDP #:
	NPI #:
ADD'L STORAGE INFORMATION	
Is the Product	Comments
Controlled Substance? No	
Controlled by State(s)? No	Registry:
ARCOS Reportable? No	Registry Program Contact Name: Phone:
Schedule No. (inc. N for non-narcotic)	Comments
Controlled Substance Code	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS
If yes, indicate which:	
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 888-238-7880
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-policy/
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this product in certain states?
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?
Restricted from US territories? (explain in comments)	
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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:	Overnight receipt available:
	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:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?