

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

						Introduction Ty	pe: New Item		x Final Version			Date:	11/7/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	on: ANDA	a. Temperature –	Indicate the USP temper	rature range for t	nis product.			
Application Number for NDA/AN	IDA/BLA; PMA/510	(k): 21644	5			NDA 505(b) Type:	NOT APPLICABLE		mperature Range	Cold – between 2		– 46° F)		
Medical Device Class, if applica	ble:													
DUNS:	11-856-3719							Oth	her Temperature Range F	Requirement	Avoid excessive h	eat. Reconstituted :	solution is stable in t 48 hours if stored u	the vial for 12
Proprietary Name (If Applicable) a		me: Daptor	mycin for Injection 350 mg/V		e Vial				(write in)		between 2° and 8	°C (36° and 46°F)		
Selling Unit NDC:	31722-215-01		Unit of Use NDC:				331722215015	No	ites		To be shipped to	o customers usin	ng proper cold sto Storage Trucks)	orage shipping
UDI			CVX Code:			MVX Code:					menious (e.g. c	Joid Facks, Cold		
Description:	Daptomycin for In	jection 350 mg/Vial, S	Single-Dose Vial						this product to be shipped				No*	
		-						ls t	this product to be shipped	to customers on c	ry ice?		No	
Active Ingredient(s):		Daptomycin						h Comtont for ton						
URL for Additional Product Inform	nation:	www.camberpharma	a com						nperature excursion que	estions:	Soma Raju			
Address:	800 Centennial Av		<u> </u>			Address 2:		-	ımber:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip: 08854	Group E-mail: somaraju@heterousa.com			<u>n</u>			
Key Contact:	Customer Service					customerservice@	camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?			No			
Product Therapeutic Classification	on:	Lipopeptide antibac	terial					Sp	ecial returns requirement	s for this product?			No	
								_						
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DI	ESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only				otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit Dose		Size:	1 single dose vial	e. Shelf life:					24	Months
if yes, enter class #		ls:	Orphan Drug Status				250 / / /	Ini	tial shelf life at launch (f different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	350 mg/vial			ORDER INFORM	IATION			
component parts			FDA Approvai Status				Sterile, nonpyrogenic, lyophilized			ORDER IN ORI	IATION			
reverse numbered?		No				Dosage Form:	cake for infusion or injection	Un	it of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 1 S	ingle Dose V	al	
latex-free?		Yes				Product Shap	Single dose vial		x Box/Carton		(Write-in, e.	g. 1 Box of 1	ງ Vials)	
preservative-free?		Yes				1 Todact Griap			Ampule					
correctional institution block?		No				Product Color	Pale yellow to light brown		x Glass		Minimum o	der quantity	?	Yes
opioid?		No	O	India			N/A		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	unit does for	No	Country of Origin	IIIuia		Product Impri	nt: N/A		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ch package t	tvno?
hospital scanning?	unit dose for	Yes	Is this product covered u	inder the					x Vial Powder Sgl			Each	Jii package i	type:
If Unit Dose, indicate NDC here:		31722-215-01	Trade Agreements Act (1		No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											/ B			
				_	Au		*If Authorized Generic, other section fields are not applicable			ARMACY ORDER				
		I. Orange Book Rating:					section fields are not applicable	Rec. sell unit to customer?			acy:			
II. Generic Equivalent to What Bra	and?:	D : '0	. 51									Each		
		Daptomycin (Sagen	nt Pharmaceuticals)					/\/\/\display in a a 4 \/	(a)					
				DSCSA) INFO	RMATION			(Write-in, e.g. 1 V	ial)			Gram		
			nt Pharmaceuticals)	DSCSA) INFO	RMATION			HCPCS J-Code:	J0878	1				
Does supplier meet DSCSA defini	ition of manufactur	DRUG SUPPL	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION GLN:	0843368117603		HCPCS J-Code:	J0878	AND PACKING I	NFORMATIO	Gram Milliliter		
Does supplier meet DSCSA definition ls product exempt from DSCSA?	ition of manufactur	DRUG SUPPL	LY CHAIN SECURITY ACT (DSCSA) INFO		0843368117603		HCPCS J-Code:	J0878	AND PACKING I	NFORMATIO	Gram Milliliter		
	ition of manufactur	DRUG SUPPL	LY CHAIN SECURITY ACT (DSCSA) INFO		0843368117603		HCPCS J-Code:	J0878		ons (US msn	Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ition of manufactur	DRUG SUPPL	LY CHAIN SECURITY ACT (Yes No	DSCSA) INFO	GLN: GCP:			HCPCS J-Code:	J0878			Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPL	LY CHAIN SECURITY ACT (Yes No	DSCSA) INFO	GLN: GCP: If yes, was o	riginal product purch	nased	HCPCS J-Code:	J0878	Dimensi	ons (US msn	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distribu	DRUG SUPPL	LY CHAIN SECURITY ACT (Yes No	DSCSA) INFO	GLN: GCP: If yes, was o	riginal product purch	-	HCPCS J-Code:	J0878 Weight Lbs. 0.03	Dimensi Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribu	DRUG SUPPL	Yes No No Yes	DSCSA) INFO	GLN: GCP: If yes, was o	riginal product purch	nased repackaged product	HCPCS J-Code:	J0878 Weight Lbs. 0.03	Dimensi Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distribu	DRUG SUPPL	Yes No No Yes No No Yes No		GLN: GCP: If yes, was o	riginal product purch	-	HCPCS J-Code: Item/Each: Box/Carton/Bund	Weight Lbs. 0.03	Dimensi Depth 1.65	ons (US msn Width 1.65	Gram Milliliter	(Cube) 8.03	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribu	DRUG SUPPL	Yes No No Yes		GLN: GCP: If yes, was o	riginal product purch	-	Item/Each: Box/Carton/Bund Inner Pack: Case:	J0878 Weight Lbs. 0.03	Dimensi Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPL	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for	repackaged product	Item/Each: Box/Carton/Bund Inner Pack:	Weight Lbs. 0.03	Dimensi Depth 1.65	ons (US msn Width 1.65	Gram Milliliter	(Cube) 8.03	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribu	DRUG SUPPL rer? ctor? oduct? GTI Saleable	Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch	-	Item/Each: Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.03	Dimensi Depth 1.65	ons (US msn Width 1.65	Gram Milliliter	(Cube) 8.03	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	s exclusive distribundexemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? stor? oduct? GTI Saleable Quantity	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch fir? ce manufacturer for	repackaged product	Item/Each: Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.03	Dimensi Depth 1.65	ons (US msn Width 1.65	Gram Milliliter	(Cube) 8.03	Pieces 1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure x	s exclusive distribundexemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? stor? oduct? GTI Saleable Quantity	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch fir? ce manufacturer for	repackaged product	Item/Each: Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.03	Dimensi Depth 1.65	ons (US msn Width 1.65	Gram Milliliter Nuts.) Height 2.95	(Cube) 8.03 575.67	Pieces 1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X	s exclusive distribun/exemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? dutor? oduct? Saleable Quantity 1	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for IN-14	repackaged product	HCPCS J-Code: Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	Weight Lbs. 0.03 ILE/ 3.11 COST INFORMATION	Dimensi Depth 1.65	ons (US msn Width 1.65 10.63	Gram Milliliter N Ints.) Height 2.95 3.93	(Cube) 8.03 575.67	Pieces 1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? 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 distribun/exemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? dutor? oduct? Saleable Quantity 1	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for IN-14	repackaged product	Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	Weight Lbs. 0.03 ILE/ 3.11 COST INFORMATION	Dimensi Depth 1.65	vendor #:	Gram Milliliter N Height 2.95 3.93	(Cube) 8.03 575.67	Pieces 1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? 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 distribun/exemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? dutor? oduct? Saleable Quantity 1	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for IN-14	repackaged product	Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA	Weight Lbs. 0.03 ILE/ 3.11 COST INFORMATION C) (\$)	Dimensi Depth 1.65	ons (US msn Width 1.65 10.63	Gram Milliliter N Height 2.95 3.93	(Cube) 8.03 575.67	Pieces 1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? 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 distribun/exemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? dutor? oduct? Saleable Quantity 1	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for IN-14	repackaged product	HCPCS J-Code: Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	Weight Lbs. 0.03 ILE/ 3.11 COST INFORMATION	Dimensi Depth 1.65	vendor #:	Gram Milliliter N Height 2.95 3.93	(Cube) 8.03 575.67	Pieces 1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? 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 distribun/exemption for pr m FDA. RFID tag(Y/N)	DRUG SUPPL rer? dutor? oduct? Saleable Quantity 1	Yes No No Yes No No Yes No No Yes No		GLN: GCP: If yes, was o direct from n Provide sour	riginal product purch nfr? ce manufacturer for IN-14	repackaged product	Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA	Weight Lbs. 0.03 ILE/ 3.11 COST INFORMATION C) (\$)	Dimensi Depth 1.65	vendor #:	Gram Milliliter N Height 2.95 3.93	(Cube) 8.03 575.67	Pieces 1 48
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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic?	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive					
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer					
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard					
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No					
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)	NFPA Storage Level:					
e. Does the product contain DEHP?	11.17. Colorge 2510.1					
·						
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?					
(if yes, answer a-e below and provide SDS)	If yes, indicate which:					
a. UN/Identification Number						
b. Proper Shipping Name						
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group	FRANK SALARIA					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number						
b. Proper Shipping Name	Is there a REMS on this product?					
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?					
d. Packing Group	Website URL:					
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No					
Passenger	Limited Distribution Requirement					
Cargo	Comments / Details: (For example, iPledge program?)					
Passenger & Cargo						
Is this a reportable quantity? No	REMS: No					
RQ Threshold:	REMS Program Manager Name: Phone:					
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)	Provider Name: DEA #:					
Limited Quantity	Site Enrollment Number assigned NCPDP#:					
Consumer Commodity, ORM-D	by Supplier: NPI #:					
Small Quantity (49 CFR 173.4)	3,326					
Special Permit; DOT-SP	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#	Registry: No					
-	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product	RETURN INSTRUCTIONS					
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? ARCOS Reportable? No Listed Chemical (List I or II) No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647					
ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No						
	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (cyclein in comments)	, INC					
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANEO	US NOTES and/or Image of Product Barcode:					
*To be shipped to customers using proper cold storage shipping methods (e.g. Cold Packs, Cold Storage	2					
To be shipped to customers using proper cold storage shipping methods (e.g. Cold Facks, Cold Storage	THURS)					



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Version 2024

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?