

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

Version 2021						Introduction Ty	rpe: New Item		x Final Version			Date:	7/22/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Applicati	on: ANDA	a Temperature	- Indicate the USP tempe	rature range for th	nis product			
Application Number for NDA/AN			ce):	21:	3709	- 11	- 1		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica														
DUNS:	11-856-3719								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable)	and Established Na	me: Dextroamph	hetamine Saccharate, Amphetamine Aspartate, Dextro	amphetamine Sulfate and Ampl	hetamine Sulfate Tablets (Mix	ked Salts of a Single-Entity Amphetamine	Product) 15 mg	1	(write in)					
Selling Unit NDC:	31722-159-01		Unit of Use NDC:			UPC:	331722159012	N	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Dextroamphetami	ne Saccharate Amn	hetamine Aspartate Dextro:	amphetamine Su	Ilfate and Amph	netamine Sulfate Tabl	ets (Mixed Salts of a Single-Entity	1	s this product to be shipped	to customers on in	e?		No	
2000puo	Amphetamine Pro		notamino riopanato, Donaro	imprioramino ou	mate and / impri	otalimo Ganato Tabi	oto (mixed cane of a cingle zinity		s this product to be shipped				No	l .
Active Ingredient(s):		Dextroamphetamin	e saccharate, amphetamine	aspartate, dextr	oamphetamine	sulfate, USP, and am	phetamine sulfate, USP				,			
						b. Contact for temperature excursion questions:								
URL for Additional Product Infor	mation:	www.camberpharm	a.com					N.	Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:		l N	Number:		732-529-042			
City:	Piscataway				NJ	Zip : 08854	Group E-mail: somaraju@heterousa.com			<u>a</u>				
Key Contact:	Customer Service					camberpharma.com_								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			lations for product in any				*Yes	l .
Product Therapeutic Classification	on:	Central nervous sys	stem (CNS) stimulant					S	Special returns requirement	s for this product?			*Yes	ı
								_						
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	l .
The product is?			Is the Product	Direct-Ship C	Only			F	Protect product (unit of sa	le) from light?			No	i
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:		-			24	Months
if yes, enter class #			Orphan Drug Status			Size.		li li	nitial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	15 mg							
if yes, list NDCs of			FDA Approval Status			ou chigan.				ORDER INFORM	ATION			
component parts						Dosage Form	Tablet							
reverse numbered?		No							Jnit of Sale		What is the I		unit?	
co-licensed?		No	Allergens Present				_		x Bottle		1 Bottle of 10			
latex-free?		Yes	Dye, Corn, /	Alcohol, Sugar		Product Shap	e: Oval		Box/Carton		(Write-in, e.g	j. 1 Box of 10) Vials)	
preservative-free?		Yes					L'abre de de e e e e		Ampule					
correctional institution block? opioid?		No No				Product Color	Light to dark peach	-	Glass Tube		Minimum or	der quantity	'	Yes
Cannabinoid?		No	Country of Origin	USA			Debossed with 'T374' with two partial bisects		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	INU	Country of Origin	UUA		Product Impri	nt: on one side, and one full bisect and two partial bisects on other side		Vial Liquid Multi		If Yes, how r	nany of whi	ch nackage t	tyne?
hospital scanning?	unit dose for		Is this product covered u	inder the					Vial Powder Sql			Each	m package t	урс.
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes				Vial Powder Multi			Inner/Carton	/Pack	
				,					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS				_						
											I			
					Au	thorized Generic	*If Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to	customer?		Rx billing un	it to pharm	acv:	
II. Generic Equivalent to What Bra		Adderall						1 100.00	- Guotomor I	Ī		Each	icy.	
ii. Generio Equivalent to What Bri	una	riddordii												
								(Write-in, e.g. 1	Vial)	l.				
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION			(Write-in, e.g. 1	Vial)	ı		Gram Milliliter		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION			(Write-in, e.g. 1	Vial)	L		Gram		
Does supplier meet DSCSA defin			Yes	(DSCSA) INFOR	RMATION GLN:	0860000397957		(Write-in, e.g. 1		AND PACKING I		Gram Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA?				(DSCSA) INFOR		0860000397957		(Write-in, e.g. 1		AND PACKING IN		Gram Milliliter		
			Yes	(DSCSA) INFOR		0860000397957		(Write-in, e.g. 1	ITEN			Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA?			Yes	(DSCSA) INFOR	GLN:	0860000397957		(Write-in, e.g. 1			IFORMATION	Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption:			Yes No	(DSCSA) INFOR	GLN: GCP:	0860000397957	nased	(Write-in, e.g. 1	Weight Lbs.	Dimensi Depth	DOIS (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:		er?	Yes No No Yes	(DSCSA) INFOR	GLN: GCP:	riginal product purcl	nased		ITEN	Dimensi	IFORMATION	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exceptic	s exclusive distribu on/exemption for pro	er?	Yes No	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	riginal product purcl	nased repackaged product	Item/Each: Box/Carton/Bur	Weight Lbs.	Dimensi Depth	DOIS (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
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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' Has FDA granted waiver/exceptic	s exclusive distribu on/exemption for pro	er?	Yes No No Yes		GLN: GCP: If yes, was or direct from m	riginal product purcl	-	Item/Each: Box/Carton/Bur Inner Pack: Case:	Weight Lbs.	Dimensi Depth	DOIS (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
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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' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	s exclusive distribu on/exemption for pro om FDA.	er? ttor? oduct? GI aleable Quantity 1	Yes No No Yes No No Yes No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	riginal product purch fir? ce manufacturer for N-14 31722159012	repackaged product	Item/Each: Box/Carton/Bur Inner Pack: Case:	Weight Lbs. 0.07	Dimensi Depth 1.52	DOTE (US msm Width 1.52 6.5	Gram Milliliter ts.) Height 2.69	(Cube) 6.21	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer Has FDA granted waiver/exceptic If yes, attach documentation from Saleable Unit of Measure X them/Each Bow/Cartor/Bundle/Inner Pack X Case	s exclusive distribu on/exemption for pro om FDA.	er? tor? oduct? GT	Yes No No Yes No No Yes No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	iginal product purcl ffr? ce manufacturer for	repackaged product	ltem/Each: Box/Carton/Bur Inner Pack: Case: Pallet:	Weight Lbs. 0.07 2.1	Dimensi Depth 1.52	IFORMATION Ons (US msm Width 1.52 6.5	Gram Milliliter ts.) Height 2.69	(Cube) 6.21 191.1	Pieces 1
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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
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? No	identify NFPA Storage Level: NFPA Storage Level:						
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	NFFA Storage Level:						
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	Hazardous Waste Identification						
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	KEIRO O REGISTRI RESTRICTIONS						
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)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Postura						
SP#	Registry: No						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:						
	Comments						
Is the Product	RETURN INSTRUCTIONS						
Controlled Substance? Yes Controlled Substance Code 1100	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes Listed Chemical (List I or II) No ARCOS Reportable? Yes If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
ARCOS Reportable? Yes If yes, indicate which: Schedule No. 2 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	product in certain states? Yes						
Restricted to hospital, clinics, and physician offices only. Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part	1301.72.						
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

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 Process	sing		
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier			
a. EDI		Cut off time:			
b. Autofax	Fax Number:				
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 Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	essing		
Expedited freight fees billed with each orde	er:	Overnight receipt available:			
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:			
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday		
Comments:		,	Tuesday		
			Wednesday		
			Thursday		
			Friday		
		Priority Overnight receipt available:			
Cla	ss of Trade Restriction:	PO Receipt Cut off time:			
No restriction: Select VES if sold to retail of	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:			
Restricted to retail pharmacy only:	larmacy, nospitals, clinics and physician offices	PO Receipt Cut off time:			
Restricted to hospital, clinics, and physician	o offices only:	Phone: Phone #			
Restricted from US territories? (explain in c		Order receipt method: Fax: Fax #:			
Comments:		EDI:			
		Overnight Fees apply:			
		Other fees apply:			
Other Data Inf	ormation Required to Process PO:	Return Instructions			
Patient Procedure Date:		Contact # if product is received damaged:			
Physician Name:		Is product returnable for credit:			
Physician/Clinic Phone #		URL/Link to returns policy:			
Physician State License #					
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain	ain states?		
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?			
	Miscellaneous Notes:				
		ADDITIONAL INFORMATION			
		Is product order for scheduled patient procedure?			
		Is product order for restocking purposes?			
		13 product order for restocking purposes:			