

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

Version 2021						Introduction Type:	New Item		Final Version			Date:		
			PRODUCT INFORMA	TION					SPECIAL HAI	NDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214959						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:														
DUNS:	82-677-4775							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a Selling Unit NDC:	31722-186-01	me: Amph	hetamine ER Capsule 10mg Unit of Use NDC:	100ct		UPC: 331	722186018	+	(write in) Notes					
UDI	31722-160-01		CVX Code:			MVX Code:	722100010	+	Notes					
								to the construct to be obtained		10		NI.	1	
Description: Oral Solid - Capsule, Capsule Shaped, Blue / Blue,10 mg and T							Is this product to be shipped Is this product to be shipped				No No			
Active Ingredient(s): Dextroamphetamine sulfate, dextroamphetamine saccharate,							+	is this product to be shippe	a to customers on	ary loc:		140	J	
amphetamine sulfateand amphetamine aspartate							b. Contact fo	b. Contact for temperature excursion questions:						
URL for Additional Product Inform									Name:		Soma Raju			
Address:		Ave (and) 800 Cente	ennial Ave, Suite 1		.	Address 2:			Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:		08854	-	Group E-mail:		somaraju(@heterousa	a.com	
Key Contact: Phone Number:	1-866-827-3647				Fax:	732-562-8788	camberpharma.com	c Special re	gulations for product in any	states?			No	1
Product Therapeutic Classification					ı ux.	702 002 0700		C. Special re	Special returns requirement		,		No	
Troduct Therapeutic Glassificatio	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,								opecial retarns requiremen	ito for tino product:			140	J
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store pro	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Only				11	Protect product (unit of s	ale) from light?			No	1
a legend device?		No	Is the Product	Neither			100ct	e. Shelf life:	r rotest product (dilit or s	uic) ii oiii iigiit i			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	10mg							
if yes, list NDCs of			FDA Approval Status			ou ongun				ORDER INFOR	MATION			
component parts reverse numbered?		IN.				Dosage Form:	Oral Solid - Capsule		Unit of Sale		What is the	NDC selling	mit?	
co-licensed?		No No	Allergens Present						x Bottle		1 bottle of 1		unit:	
latex-free?		Yes	7 morgono i rocom			Described Observe	Capsule Shaped		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule				,	
correctional institution block?						Product Color:	Blue / Blue		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	10 mg and T		Vial Liquid Sgl		If Yee hem		:	
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for	No	Is this product covered to	inder the					Vial Liquid Multi Vial Powder Sql			Each	ich package t	type?
If Unit Dose, indicate NDC here:		140	Trade Agreements Act (Vial Power Multi		24	Inner/Cartor	1/Pack	
				,					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS				_						
					Aut		uthorized Generic, other			HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating: AB section fields are not applicable					ion fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Bra	and?:	Adderall XR						00/-1/- 1	- 4 \ / / - D			Each		
		DRUG SUPE	PLY CHAIN SECURITY ACT	(DSCSA) INFORMA	TION			(Write-in, e.g	g. 1 Viai)			Gram Milliliter		
		DROG GOLL	ET OTIAIN OLOGICITT AOT	(DOGGA) IIII GRIIIA	TION							Ivillilitei		
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes	GL	LN:	0331722000000			ITE	M AND PACKING I	INFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:				GC	CP:			1	Wetstalle	Dimens	sions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:								·	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchase	ed	Item/Each:	0.936		1.876	3.225	0	1
Is product sold by manufacturer's			Yes No	_	rect from m			Box/Carton/						
Has FDA granted waiver/exception If yes, attach documentation from		oduct?	INU	Pr	ovide sourc	ce manufacturer for rep	ackaged product	Inner Pack:	Bundle/				0	
ii yes, attacii documentation no	III I DA.							Case:			-			
		GT	TIN AND HIBCC PRODUCT I	NFORMATION					2.6	12.3	8.3	3.8	387.942	24
								Pallet:					0	
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14						•	
X Item/Each		1			0033	31722186018			COST INFORMATION			WHOLESAL	ER USE ONL	V
Box/Carton/Bundle/Inner Pack X Case		24			1025	31722186015			COST INFORMATION			WHOLESAL	ER USE UNL	.17.
X Case Pallet		24			1033	31122100013		Regular Cos	st		Vendor #:			
								Invoice Cost		\$70.00	Whsl. Code	#:		
										, , , , , ,	Fineline Co			
								As of date:						
								11						
ļ !			August and Conference	ATA OUEET (00.5)		- Harris BACKAGE (115	DT LABEL AND DUCTO TO	DDODUCT DATE:	(AOINO I DARCORE					
*Please provide any additional inf	formation on no	2	Attach copy of SAFETY D	ATA SHEET (SDS)	or non hazai		ERT, LABEL AND PHOTO OF I	PRODUCT PACK						
*Please provide any additional inf	iormation on page	4.				dee new p. 3 for Desi	gnated Drop Ship Only.		Signature:					



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA?	No	DEMC	r REGISTRY RESTRICTIONS			
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No No			
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	No	Phone: DEA #: NCPDP#: NPI #:			
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments				
SP#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments		1 Horie.		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. Yes If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:	Yes	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only:	contact - customerservice@camberpharma.com					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:	No	1 30, milor states: Other requirements: Offilinents:				
MI	SCELLANEO	DUS NOTES and/or Image of Product Barcode:				



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 D	Orop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
	x Number:	
	x Number:	Shipping lead time of PO: Hours Days
	one No.:	China cama day far nayt day receipts
e. Supplier Web Site only Site Minimum Order Quantity:	e Address:	Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Ships regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other De	esignated 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:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Class of Trade Restr	riction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals	c clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	s, clinics and physician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone: Phone #:
Restricted from US territories? (explain in comments)		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Require	ed 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 states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
Miscellaneous No	otes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?