

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

Version 2024							Introduction T	Гуре:	New Item		x Final Ve	rsion			Date:	11/8	/2024
			PROD	UCT INFORMA	TION						SPEC	CIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.					Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	DA/BLA; PMA/510	0(k):	217442				NDA 505(b) Type:	:	NOT APPLICABLE		Temperature Rang		Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:																
DUNS:	11-856-3719										Other Temperatur	e Range F	Requirement	Excursions p	permitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		lame:	Lisdexamfetamine								(write in)						
Selling Unit NDC:	31722-352-01			nit of Use NDC:			UPC: MVX Code:	331722	2352017		Notes						
UDI				VX Code:			MVX Code:										-
Description:	Lisdexamfetamin	ne Dimesylate 0	Capsules 30 mg										d to customers on ic			No	
Active Ingredient(s): Lisdexamfetamine dimesylate						Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions:											
			roharma.com							b. Contact for		ırsion que	estions:	0 D-!			
URL for Additional Product Inform Address:	800 Centennial A		rpnarma.com			1	Address 2:				Name:			Soma Raju 732-529-042	22		
City:	Piscataway	ave, Suite i				State: NJ Zip: 08854							u@heterousa.com				
Key Contact:	Customer Service	e				Email:				- Group E-mail.				<u>oomaraja(a)</u>			
Phone Number:	1-866-827-3647					Fax:				c. Special regulations for product in any states?						*Yes	1
Product Therapeutic Classificatio	n:	Central nerv	ous system (CNS):	stimulant						'	Special returns re	quirement	s for this product?			*Yes	
			, , ,			-					•						
	ADDIT	IONAL PRODU	JCT INFORMATIO	N			PRODUCT	DESCRI	PTION INFORMATION	d. Store prod	uct (unit of sale) u	pright?				No	1
The product is?			Is the Pi	oduct	Direct-Ship C	Only					Protect product (unit of sa	ile) from light?			No	ī
a legend device?		No	Is the Pi		Neither	-	Ci		100 ct	e. Shelf life:			,			24	Months
if yes, enter class #			Orphan	Drug Status			Size:				Initial shelf life at	launch (i	if different):				Months
a product kit?		No					Strength:		30 mg								
if yes, list NDCs of			FDA Ap	proval Status			Ou chigan.						ORDER INFORM	IATION			
component parts		1					Dosage Forn	n:	Hard gelatin capsule					1471	NDO III	140	
reverse numbered? co-licensed?		No	A !!	- Dunnant			_				Unit of Sale x Bottle			1 Bottle of 1	NDC selling	unit?	
latex-free?		No Yes	Allerger	s Present					Capsule		x Bottle Box/Car	ton			g. 1 Box of 1) Viale)	
preservative-free?		Yes		Corn, Alc	ohol, Animal		Product Sha	pe:	Capsule		Ampule	ton		(vviite-iii, e.	.g. 1 DOX 01 11	J Viais)	
correctional institution block?		No							Orange opaque cap and		Glass			Minimum o	rder quantity	?	Yes
opioid?		No					Product Cold		white opaque body		Tube						
Cannabinoid?		No	Country	of Origin	USA		Product Imp	rint:	Cap imprinted with 'AC' in black ink		Vial Liqu	ıid Sgl					
If Unit Dose, is item bar coded to u	unit dose for						r roduct imp	· · · · · ·	and body imprinted with '30' in black ink		Vial Liqu				many of whi	ch package	type?
hospital scanning?				oduct covered i	under the						Vial Pow			24	Each		
If Unit Dose, indicate NDC here:			Trade A	greements Act (TAA)?	Yes						vder Multi			Inner/Carton	/Pack	
											Other: W	vrite in			Case		
			FOR GEN	ERIC DRUG PR	ODUCIS												
						Aı	thorized Generic	*If Auth	norized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB								fields are not applicable	Poc coll unit	to customor?				nit to phorm	2011	
II. Generic Equivalent to What Bra		Vyvanse							Rec. sell unit to customer? Rx billing unit to pharmacy:				acy.				
ii. Generic Equivalent to What Brand:.											Gram						
		DRUG	SUPPLY CHAIN S	ECURITY ACT	(DSCSA) INFOR	RMATION				HCPCS J-Co					Milliliter		
															-		
Does supplier meet DSCSA defini	tion of manufactu	ırer?	Ye	s		GLN:	0843368117603					ITEM	AND PACKING IN	IFORMATIO	N		
Is product exempt from DSCSA?			No														
If yes, select exemption:						GCP:					Wein	ht Lbs.		ons (US msn		Volume	Saleable #
Other exemption - Write in:										1	- Treig		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Ye	ne .	-		riginal product pur	cnased		Item/Each:	0	.09	1.88	1.88	3.23	11.42	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Y E		-	direct from n	ntr? ce manufacturer fo	r ronaci	kaged product	Box/Carton/B	Rundlo/						
If yes, attach documentation from		orouuct?				Flovide Soul	ce manuracturer to	пераст	kageu product	Inner Pack:	suriule/						
,										Case:			40.0				0.4
			GTIN AND HIB	CC PRODUCT I	NFORMATION						2	.09	12.3	8.3	3.8	387.94	24
										Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC			GTI	N-14		Unit of Use GTIN-14								
		Quantity				_		_									
x Item/Each	N	1				003	31722352017	_			COST INFOR	MATION			WHOLESAL	ED HEE ON	V.
Box/Carton/Bundle/Inner Pack X Case	N	24				102	31722352014	-			COST INFOR	MATION			WHOLESAL	EK USE UNL	
X Case Pallet	IN	24				103	01122332014			Regular Cost				Vendor #:			
T GHOS										Invoice Cost			\$932.00	Whsl. Code	#:		
													\$552.50	Fineline Co			
										As of date:	9/18/202	24]			
Ш																	
		_	Attach cop	y of SAFETY D	ATA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF P ated Drop Ship Only	PRODUCT PACK	AGING and BARCO	DE.					
*Please provide any additional inf																	



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? No	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? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive 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? No	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 a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
a. Orvinderinitication Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
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? No (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: Phone: DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION is the Product	Comments						
Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. Yes Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
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) No Comments:	contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? DEA Form 222 or its electronic equivalent is required for all returns in all states.						
Општоно.	DELY STITE ELE STOCK ON CONTROL CONTROL TO CONTROL OF AN I COURTS IT AN STATE OF						
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	ırt 1301.72.						



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

Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing						
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier						
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:						
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