

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

						Introduction Ty	/pe: New Item		x Final Version			Date:	11/11	/2024
			PRODUCT INFORMA	TION					SPECIAL 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	IDA/BLA; PMA/51	0(k): 2174	442			NDA 505(b) Type:	NOT APPLICABLE		perature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	11-856-3719							Othe	er Temperature Range I	Requirement	Excursions	permitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		lame: Lisd	dexamfetamine Dimesylate Cap						(write in)					
Selling Unit NDC: UDI	31722-351-01		Unit of Use NDC:			UPC: MVX Code:	331722351010	Note	es					
-			CVX Code:			WVX Code.								1
Description:	Lisdexamfetamin	ne Dimesylate Capsi	ules 20 mg						is product to be shipped				No No	
Active Ingredient(s):  Lisdexamfetamine dimesylate						Is this product to be shipped to customers on dry ice?  b. Contact for temperature excursion questions:				INO	J			
URL for Additional Product Inforn	nation:	www.camberphar	rma com					b. Contact for tem		estions:	Soma Raju			
Address:	800 Centennial A		ma.com			Address 2:			nber:		732-529-042	23		
City:	Piscataway				State:			Group E-mail:			somaraju@heterousa.com			
Key Contact:	Customer Servic				Email:		camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ons for product in any				*Yes	
Product Therapeutic Classificatio	on:	Central nervous s	system (CNS) stimulant		1			Spe	cial returns requirement	s for this product?			*Yes	
	ADDIT	TIONAL PRODUCT I	INFORMATION			PRODUCT-D	ESCRIPTION INFORMATION	d Store product (	ınit of sale) upright?				No	1
The product is 2	— ADDIT	IONAL I RODUCI		Direct-Ship C	)ply	- TRODUCT D	LOOKII HON INFORWATION			ala) fuama limbto				]
The product is? a legend device?		No	Is the Product Is the Product	Neither	Tily		100 ct	e. Shelf life:	tect product (unit of sa	ile) from light?			No 24	Months
if yes, enter class #		INU	Orphan Drug Status	Tectures		Size:	100 Ct		al shelf life at launch (	if different):			24	Months
a product kit?		No				Ctuan ath.	20 mg							1
if yes, list NDCs of			FDA Approval Status			Strength:	_			ORDER INFORM	ATION			
component parts						Dosage Form	Hard gelatin capsule							
reverse numbered? co-licensed?		No	Allannana Drasant						t of Sale x Bottle		1 Bottle of 1	NDC selling	unit?	
latex-free?		No Yes	Allergens Present				Capsule		Box/Carton			g. 1 Box of 1	) Vials)	
preservative-free?		Yes	Corn, Alco	ohol, Animal		Product Shap	e:		Ampule		(**************************************	g. 1 Box 01 1	o viaio,	
correctional institution block?		No				Product Color	Ivory opaque cap and		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				r roduct color	ivory opaque body		Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impri	nt: Cap imprinted with 'AC' in black ink and body imprinted with '20' in black		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		In this product covered t	inder the			ink		Vial Liquid Multi Vial Powder Sql			many of whi	ch package i	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1	TAA)?	Yes				Vial Powder Sgi Vial Powder Multi		24	Inner/Carton	/Pack	
				,					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
				_	Au		*If Authorized Generic, other			IARMACY ORDER				
		I. Orange Book Rating:			section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:				acy:		
II. Generic Equivalent to What Bra	II. Generic Equivalent to What Brand?:						[ Eacl							
		Vyvanse						(Mrito in o.g. 1 Vic	N)	_		-		
			PLY CHAIN SECURITY ACT (	(DSCSA) INFOR	MATION			(Write-in, e.g. 1 Via	al)	_		Gram		
			PLY CHAIN SECURITY ACT (	(DSCSA) INFOR	RMATION			(Write-in, e.g. 1 Via		1		Gram Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	DRUG SUP	Yes	(DSCSA) INFOR	RMATION GLN:	0860000397957				I AND PACKING IN	IFORMATIO	Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufactu	DRUG SUP	,	(DSCSA) INFOR	GLN:	0860000397957						Gram Milliliter		
Is product exempt from DSCSA?  If yes, select exemption:	ition of manufactu	DRUG SUP	Yes	(DSCSA) INFOR		0860000397957				Dimensi	ons (US msn	Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in:	ition of manufactu	DRUG SUP	Yes No	(DSCSA) INFOR	GLN: GCP:		hasad	HCPCS J-Code:	Weight Lbs.	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?		DRUG SUP	Yes	(DSCSA) INFOR	GLN: GCP: If yes, was or	riginal product purcl	hased		ITEN	Dimensi	ons (US msn	Gram Milliliter		
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in:	s exclusive distrib	DRUG SUP	Yes No	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	riginal product purcl	hased repackaged product	HCPCS J-Code:	Weight Lbs.	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 distrib on/exemption for p	DRUG SUP	Yes No No Yes	(DSCSA) INFOR	GLN: GCP: If yes, was or direct from m	riginal product purcl		HCPCS J-Code:	Weight Lbs.	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 distrib on/exemption for p	DRUG SUP	Yes No No Yes No		GLN: GCP: If yes, was or direct from m	riginal product purcl		HCPCS J-Code:  Item/Each:  Box/Carton/Bundle	Weight Lbs.	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 distrib on/exemption for p	DRUG SUP	Yes No No Yes		GLN: GCP: If yes, was or direct from m	riginal product purcl		HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack:  Case:	Weight Lbs.	Dimensi Depth 1.88	ons (US msn Width 1.88	Milliliter  N  nts.)  Height  3.23	(Cube) 11.42	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 from	s exclusive distrib on/exemption for p m FDA.	DRUG SUP	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m	riginal product purcl ofr? ce manufacturer for	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack:	Weight Lbs.	Dimensi Depth 1.88	ons (US msn Width 1.88	Milliliter N nts.) Height 3.23	(Cube) 11.42	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 distrib on/exemption for p	DRUG SUP	Yes No No Yes No		GLN: GCP: If yes, was or direct from m	riginal product purcl		HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack:  Case:	Weight Lbs.	Dimensi Depth 1.88	ons (US msn Width 1.88	Milliliter N nts.) Height 3.23	(Cube) 11.42	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 from	s exclusive distrib on/exemption for p m FDA.	DRUG SUP urer?  putor?  product?  G  Saleable	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source	riginal product purcl ofr? ce manufacturer for	repackaged product	HCPCS J-Code:  Item/Each: Box/Carton/Bundle Inner Pack: Case: Pallet:	Weight Lbs.  0.08  1.96	Dimensi Depth 1.88	ons (US msn Width 1.88	Gram Milliliter  N  nts.)  Height  3.23	(Cube) 11.42 387.94	Pieces 1 24
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 froi  Saleable Unit of Measure  X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl off? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each: Box/Carton/Bundle Inner Pack: Case: Pallet:	Weight Lbs.	Dimensi Depth 1.88	ons (US msn Width 1.88	Milliliter N nts.) Height 3.23	(Cube) 11.42 387.94	Pieces 1 24
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 from  Saleable Unit of Measure    X	s exclusive distrib ordexemption for p m FDA. RFID tag(Y/N)	DRUG SUP urer?  poutor?  product?  G  Saleable Quantity	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl fir? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack: Case:  Pallet:	Weight Lbs.  0.08  1.96	Dimensi Depth 1.88	ns (US msn Width 1.88	Gram Milliliter  N  nts.)  Height  3.23	(Cube) 11.42 387.94	Pieces 1 24
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 froi  Saleable Unit of Measure  X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl off? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack:  Case:  Pallet:  Regular Cost	Weight Lbs.  0.08  1.96  COST INFORMATION	Dimensi Depth 1.88	ns (US msn Width 1.88 8.3	Gram Milliliter  N  nts.)  Height  3.23  3.8	(Cube) 11.42 387.94	Pieces 1 24
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 from  Saleable Unit of Measure    X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl off? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack: Case:  Pallet:	Weight Lbs.  0.08  1.96  COST INFORMATION	Dimensi Depth 1.88	ns (US msn Width 1.88	Gram Milliliter  N  Height  3.23  3.8  WHOLESALI	(Cube) 11.42 387.94	Pieces 1 24
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 from  Saleable Unit of Measure    X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl off? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack:  Case:  Pallet:  Regular Cost	Weight Lbs.  0.08  1.96  COST INFORMATION	Dimensi Depth 1.88	Vendor #:	Gram Milliliter  N  Height  3.23  3.8  WHOLESALI	(Cube) 11.42 387.94	Pieces 1 24
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 from  Saleable Unit of Measure    X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	Yes No  No  Yes No  TIN AND HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source GTII	riginal product purcl off? ce manufacturer for N-14	repackaged product	HCPCS J-Code:  Item/Each:  Box/Carton/Bundle Inner Pack: Case:  Pallet:  Regular Cost Invoice Cost (WAC	Weight Lbs.  0.08  1.96  COST INFORMATION  (5) (\$)	Dimensi Depth 1.88	Vendor #:	Gram Milliliter  N  Height  3.23  3.8  WHOLESALI	(Cube) 11.42 387.94	Pieces 1 24
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 from  Saleable Unit of Measure    X	s exclusive distrib infexemption for p m FDA.  RFID tag(Y/N)	DRUG SUP urer?  poutor? product?  G Saleable Quantity 1	No No Yes No STIN AND HIBCC PRODUCT II HIBCC	NFORMATION	GLN: GCP: If yes, was or direct from m Provide source GTII  003	riginal product purch fr? ce manufacturer for N-14 331722351010	repackaged product	HCPCS J-Code:  Item/Each: Box/Carton/Bundle Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (WAC) As of date:	Weight Lbs.  0.08  1.96  COST INFORMATION  9/18/2024	Dimensi Depth 1.88	Vendor #:	Gram Milliliter  N  Height  3.23  3.8  WHOLESALI	(Cube) 11.42 387.94	Pieces 1 24



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD 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 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?  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 SDS) 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 e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics
Is this product regulated for shipment by IATA?	EFA Hazardous waste code.
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification 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  NO  Phone:  DEA #: NCPDP#: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No
	Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION	Comments
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Yes  Controlled Substance Code  Listed Chemical (List I or II)  No  If yes, indicate which:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged: 1-866-827-3647
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  Restricted to retail pharmacy only:  No	contact - customerservice@camberpharma.com
Restricted to hospital, clinics, and physician offices only:  No Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	t 1301.72.



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

#### 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?