

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

Version 2021						Introduction Type	e: New Item		Final Version			Date:	7/30)/2021
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			ce):	21:	3709				perature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			,						,					
DUNS:	826774775							Othe	er Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Na	me: Dextro	amphetamine Saccharate, A	mphetamine As	spartate, Dextro	amphetamine Sulfate a	nd Amphetamine Sulfate	1	(write in)	·				
Selling Unit NDC:	31722-158-01		Unit of Use NDC:			UPC:		Note	es					
UDI			CVX Code:			MVX Code:								
Description:	Oral Solid Tablet,	Round beveled edge	e tablet, light to dark peach, o	lebossed with T	over 373 on or	ne side and one full bise	ct and two partial bisects on	ls th	is product to be shippe	d to customers on i	ce?		No	1
•	other side.	· ·					•		is product to be shippe				No	
Active Ingredient(s):		Dextroamphetamin	e Saccharate, Amphetamine	Aspartate, Dext	troamphetamine	e Sulfate and Amphetan	nine Sulfate Tablets (Mixed	1						_
Salts of a Single Entity Amphetamine Product)					b. Contact for temperature excursion questions:									
URL for Additional Product Inforr		www.camberph	arma.com		Address O			Nan			Soma Raju			
Address:	800 Centennial Av	ve			Address 2: State: NJ 08854				nber:		732-529-042			
City:	Pisacataway				State:			Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service 732-529-0430)			Email:	732-562-8788	ocamberpharma.com			-1-10				
Phone Number:		0	-1 0111-		Fax:	132-302-0100			ons for product in any					-
Product Therapeutic Classification	on:	Central Nervous Sy	stem Stimulants					Spe	cial returns requiremen	ts for this product?				
	ADDITI	ONAL PRODUCT IN	FORMATION			PROPUST DES	CODUCTION INCODES ATION	1						7
	ADDITI	ONAL PRODUCT IN				PRODUCT DES	SCRIPTION INFORMATION	11	unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				tect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100CT	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status				10.5110	Initi	al shelf life at launch	if different):			24	Months
a product kit?		No	FDA Approval Status			Strength:	12.5MG			ORDER INFOR	MATION			
if yes, list NDCs of component parts			FDA Approvai Status				Oral Solid - Tablet			OKDEK INFORI	VIATION			
reverse numbered?		No				Dosage Form:	Oral Solid - Tablet	Unit	t of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 10			
latex-free?		Yes					Round		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule		,	,	,	
correctional institution block?		Yes				Product Color:	Light to dark peach		Glass		Minimum or	der quantity	/?	Yes
opioid?		Yes				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint	Upper: T over 373; Lower:		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					. roudet imprint			Vial Liquid Multi				ich package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	IAA)?				II —	Vial Power Multi			Inner/Carton	n/Pack	
				AD110T0					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Δ.,	thorized Generic *If	Authorized Generic, other		PI	ARMACY ORDER	/ BILL LINIT			
	AD						ection fields are not applicable	Rec. sell unit to cu		IARRINAOT ORDER				
I. Orange Book Rating:	AB	Adderall						Rec. sell unit to cu	istomer?	T	Rx billing u		acy:	
II. Generic Equivalent to What Bra	and ::	Adderall						(Write-in, e.g. 1 Via	الد			Each Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			(vviite-iii, e.g. i via	ai)			Milliliter		
		51100 001 1 1		,5000,1, 0.								IVIIIIIIICI		
Does supplier meet DSCSA defin	ition of manufactur	er?	Yes		GLN:	0331722000000			ITEI	AND PACKING I	NFORMATION	ı		
Is product exempt from DSCSA?			No											
If ves. select exemption:					GCP:			i		Dimens	ions (US msn	its.)	Volume	Saleable #
Other exemption - Write in:								1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product		Item/Each:	0.06		1.52	2.69	0	1
Is product sold by manufacturer's	s exclusive distribu	itor?	No		purchased di	rect from mfr?	-		0.06		1.52	2.09	0	!
Has FDA granted waiver/exception		oduct?	No		Provide sour	ce manufacturer for re	packaged product	Box/Carton/Bundle	e/				0	
If yes, attach documentation fro	om FDA.							Inner Pack:						
								Case:	1.5	9.8	6.5	3	191.1	24
		GTI	IN AND HIBCC PRODUCT I	NFORMATION										
Saleable Unit of Measure		alaabla Oosaalla	LUDOO		OTI		Helical Helical OTIN 44	Pallet:					0	
X Item/Each	S	aleable Quantity	HIBCC			N-14 31722158015	Unit of Use GTIN-14							
Box/Carton/Bundle/Inner Pack					003	01122100010			COST INFORMATION			NHOLESAL	ER USE ONL	LY:
X Case		X			103	31722158012								
Pallet					1			Regular			Vendor #:			
								Invoice Cost (WAC	C) (\$)	\$37.28	Whsl. Code	#:		
								11			Fineline Co			
								As of date:						
								11						
<u>'</u>								Ц						
*Please provide any additional in			Attach copy of SAFETY DA	ATA SHEET (SD	OS) or non haza		SERT, LABEL AND PHOTO OF F		G and BARCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MAT	ERIAL HAZ	ARD 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?	No	X Organic	Corrosive			
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer			
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard			
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,				
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:				
(If yes, attach SDS with special instructions.)		NFPA Storage Level:				
e. Does the product contain DEHP?	No					
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	No			
(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		FPA Usersham Waste Only				
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics			
Is this product regulated for shipment by IATA?	No	·				
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS			
a. UN/Identification Number						
b. Proper Shipping Name		Is there a REMS on this product?	No			
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:				
e. Inhalation Hazard?	No	Website ORL.				
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No			
Passenger Cargo		Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
Passenger & Cargo		Confinents / Details. (For example, iFledge program?)				
		2540	N			
Is this a reportable quantity? No		REMS:	No Phase			
RQ Threshold: Is this a marine pollutant? No		REMS Program Manager Name: Supplier Manages REMS registry exclusively:	Phone:			
Is this a manne pollutant? NO Secretary 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);						
SP#		Registry:				
		Registry Program Contact Name:	Phone:			
ADD'L STORAGE INFORMATION		Comments				
Is the Product						
Controlled Substance? Yes Controlled Substance Code 9193		R	ETURN INSTRUCTIONS			
Controlled by State(s)? No Listed Chemical (List I or II)	No					
ARCOS Reportable? Yes If yes, indicate which:		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	Yes					
Restricted to retail pharmacy only:	No	On a sint an addition and additional addi				
		Special regulations or returns requirements for this product in certain states?				
Restricted to hospital, clinics, and physician offices only:	No	'				
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?				
Comments:						
MIS	CELLANEO	US NOTES and/or Image of Product Barcode:				
		_				



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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:		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-	cessing			
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 pl	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 physiciar	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 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?				
		10 product order for restocking purposes:				