

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

Version 2021						Introduction 1	Туре:	New Item		x Final Version			Date:	1/2/	2023
		PR	ODUCT INFORMAT	ΓΙΟΝ						SPECIAL HAI	NDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANI	DA/BLA (drug); PMA/510(k)	(med device):		21	5534					emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab															
DUNS:	82-677-4775									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		Sapropterin Dih	ydrochloride Tablet	100mg 120ct						(write in)					
Selling Unit NDC:	31722-045-12		Unit of Use NDC:			UPC:	33172204	45124	1	lotes					
UDI			CVX Code:			MVX Code:									
Description:	Sapropterin Dihydrochloride	Tablet 100mg -								s this product to be shippe				No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Sapropterin Dihydrochloride b. Contact for temperature excursion questions:															
URL for Additional Product Information: www.camberpharma.com								Name: Soma Raju							
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:	Address 2:			Number:						
City:	Piscataway State:				NJ	NJ Zip: 08854			Group E-mail:		732-529-042 somaraju@h		<u>n</u>		
Key Contact:	Customer Service	Customer Service Email:			Email:	customerservice@camberpharma.com						-			
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regu	ations for product in any	/ states?			No	
Product Therapeutic Classification	n: Phenyla	anine Hydroxylase A	Activator						5	Special returns requirement	nts for this product?			No	
									1						
	ADDITIONAL PR	ODUCT INFORMAT				PRODUCT	DESCRIPT	ION INFORMATION	-	t (unit of sale) upright?				No	
The product is?			Product	Direct-Ship C	Only					Protect product (unit of s	ale) from light?			No	
a legend device?	No		Product	Neither		Size:	12	20ct	e. Shelf life:					24	Months
if yes, enter class #		Orpha	an Drug Status				10	00mg	1	nitial shelf life at launch	(if different):			24	Months
a product kit? if yes, list NDCs of	No	FDA	Approval Status			Strength:		Jong			ORDER INFOR	MATION			
component parts			Approvalotatus				0	ral Solid - Tablet							
reverse numbered?	No					Dosage Forr	m:			Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allerg	gens Present						Γ	x Bottle		1 bottle of 12	20 tablets		
latex-free?	Yes					Product Sha	R	ound		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	No					i roudet ond				Ampule					
correctional institution block?	No					Product Cole	or: Of	f-white to light yellow, mo	_	Glass		Minimum or	der quantity	?	Yes
opioid?	No	Court	tax of Origin	India				4"	_	Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	No No	Coun	try of Origin	India		Product Imp		1" one side and plain on	_	Vial Liquid Sgl Vial Liquid Multi		If Yes, how	many of whi	ch nackado	huno?
hospital scanning?	No	Is this	s product covered u	nder the			01	Tone side and plain on	-	Vial Powder Sql			Each	cii package	iype:
If Unit Dose, indicate NDC here:	110		Agreements Act (T		No				-	Vial Power Multi			Inner/Cartor	/Pack	
			<b>.</b>							Other: Write In			Case		
-		FOR GE	ENERIC DRUG PRO	ODUCTS											
					Au	thorized Generic		ized Generic, other		P	HARMACY ORDER	R / BILL UNIT			
	AB						section fi	elds are not applicable	Rec. sell unit to	customer?	_	Rx billing u		acy:	
II. Generic Equivalent to What Brand?: Kuvan								Each							
	סח	UG SUPPLY CHAIN							(Write-in, e.g. 1 Vial) Gram Milliliter						
	DR	OG SUPPLI CHAIN	FOLCORITI ACT (I	DOCOA) INFOR					-				willinter		
Does supplier meet DSCSA definit	ion of manufacturer?		Yes	7	GLN:	0331722000000				ITE	M AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?		No													
If yes, select exemption:					GCP:						Dimens	ions (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No				riginal product pur	chased		Item/Each:	0.15		1.81	3.19	0	1
Is product sold by manufacturer's			Yes	_	direct from m							1.01	0.10	, i i i i i i i i i i i i i i i i i i i	
Has FDA granted waiver/exception			No		Provide sour	ce manufacturer fo	or repacka	ged product	Box/Carton/But Inner Pack:	ndle/				0	
If yes, attach documentation from	n FDA.								Case:						
		GTIN AND H	IBCC PRODUCT IN	FORMATION					Case.	4.6	11.75	8	4.5		24
		-							Pallet:					0	
Saleable Unit of Measure	Saleable C	uantity HIBC	С			N-14		Unit of Use GTIN-14						0	
X Item/Each	1				003	31722045124						_			
Box/Carton/Bundle/Inner Pack							-			COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case	24				203	31722045128	-		Denul - Cool			Vand-"#			
Pallet							-		Regular Cost Invoice Cost (W	(AC) (\$)	£0.040.00	Vendor #: Whsl. Code	#-		
							-		invoice Cost (W	(v)	\$3,240.00	Fineline Code			
									As of date:						
	-														
		Attach c	copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT,	LABEL AND PHOTO OF P	RODUCT PACKAG	ING and BARCODE.					
*Please provide any additional info	ormation on page 2.					See new p. 3 for	r Designate	ed Drop Ship Only.	5	Signature:					

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

Version 2021 For Design	nated Drop Ship Only Products, Please Use Page 3
MATERIAL H	IAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? 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 Is this product regulated for shipment by DOT? No	x       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         Is the product a NIOSH hazardous drug?       No
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	If yes, indicate which:  Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:
Is the product restricted for air shipment? If so, indicate restriction:          No         Passenger         Cargo         Passenger & Cargo         Is this a reportable quantity?	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: No
RQ Threshold:       No         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)         Special Permit; DOT-SP	REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS
Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If yes, indicate which:	Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     Yes       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       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     Ves	contact - customerservice@camberpharma.com         Special regulations or returns requirements for this product in certain states?         No         If so, which states? Other requirements? Comments?
MISCELLAN	EOUS 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 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:       Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?