

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

Version 2021						Introduction Type:	New Item		x Final Version			Date:	3/17	/2022	
			PRODUCT INFORMA	TION					SPECIAL HAI	NDLING AND STOR	RAGE 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 (drug); PN	//A/510(k)(med dev	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)												
Medical Device Class, if applica			·						· -						
DUNS:	82-677-4775							_	Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a		ime: Laco	samide Tablets 200mg 60ct					I	(write in)						
Selling Unit NDC:	31722-815-60		Unit of Use NDC:				722815604		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Oral Solid - Table	t, oval shaped, blue	Upper: '15' Lower: 'J'	T	Is this product to be shippe	d to customers on i	ce?		No						
									Is this product to be shippe	d to customers on o	dry ice?		No		
Active Ingredient(s): Lacosamide															
								b. Contact for temperature excursion questions:							
	RL for Additional Product Information:  Idress: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1					Address 2:		-	Name:		Soma Raju	732-529-0423			
Address:	Piscataway	al Ave (and) 800 Centennial Ave, Suite 1  State:							Number: Group E-mail:			23 @heterousa			
City: Key Contact:	Customer Service						camberpharma.com	-	Group E-mail:		Somaraju	<u>wneterous</u>	a.com		
Phone Number:	1-866-827-3647	Fax:				732-562-8788	camber pharma.com	c Special re	gulations for product in any	states?			No	1	
Product Therapeutic Classification								o. opeciai ie	Special returns requiremen				No	1	
l round morapound diagonicum			opoolar rotamo roquiromor	no for tino product.			- 110	1							
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									d. Store product (unit of sale) upright?						
					dv				Protect product (unit of sale) from light?			No			
The product is? a legend device?		No	Is the Product	Neither	y		60ct	e. Shelf life:	Protect product (unit of s	ale) Irom ngmr			24	Months	
if yes, enter class #		140	Orphan Drug Status			Size:	0001	C. Onen me.	Initial shelf life at launch	(if different):			2.7	Months	
a product kit?		No				Strength:	200mg		minual stien the at launch (it unferency.						
if yes, list NDCs of						ORDER INFORM	MATION								
component parts						Dosage Form:	Oral Solid - Tablet								
reverse numbered?		No				Dosage Form.			Unit of Sale			NDC selling	unit?		
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 6				
latex-free?		Yes				Product Shape:	Oval		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		Yes				-	Disco		Ampule						
correctional institution block? opioid?		No				Product Color:	Blue		Glass Tube		Wilnimum o	rder quantity	11	Yes	
Cannabinoid?		No	Country of Origin	India			Upper: '15' Lower: 'J'		Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for	140	country of origin	maia		Product Imprint:	opposit to comon o		Vial Liquid Multi		If Yes, how	many of whi	ich package	type?	
hospital scanning?	unii 4000 101		Is this product covered u	under the					Vial Powder Sql		24	Each	pg-	-51	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Cartor	/Pack		
				-					Other: Write In			Case			
FOR GENERIC DRUG PRODUCTS															
	Authorized Generic ** 1f Authorized Generic, other							PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB					sec	tion fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	acy:			
II. Generic Equivalent to What Brand?: Vimpat										Each					
								(Write-in, e.g	j. 1 Vial)			Gram			
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORM	MATION							Milliliter			
Does supplier meet DSCSA definition of manufacturer?  Yes GLN: 0331722000000									ITE	M AND PACKING I	NEODMATIO	N			
Is product exempt from DSCSA?	ition of manufactur	err	No No	⊢ '	GLIN.	0331722000000				VI AND I ACKING I	INI OKWATIO	IN			
			110							Dimensi	: /IIC	\			
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.	Dimens	ions (US msr Width	nts.) Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		f vos was or	iginal product		Item/Each:		Бериі	1		·		
Is product sold by manufacturer's	s exclusive distribu	itor?	No			rect from mfr?		Item/Lucii.	0.14		1.91	3.11	0	1	
Has FDA granted waiver/exceptio			No			ce manufacturer for rep	ackaged product	Box/Carton/	Bundle/				0		
If yes, attach documentation fro	m FDA.							Inner Pack:					0		
								Case:	4.2	11.5	8	4.5	0	24	
		G1	IN AND HIBCC PRODUCT I	NFORMATION								1.0			
Onlankin Hall of Manager	_							Pallet:					0		
Saleable Unit of Measure	S	aleable Quantity	HIBCC			N-14	Unit of Use GTIN-14								
x       tem/Each   1     00331					31722815604		COST INFORMATION			WHOLESALER USE ONLY:					
X Case		24			203	31722815608			COST IN ORMATION			WIIOLLSAL	LK USL UNI	-1.	
Pallet					200	<u></u>		Regular			Vendor #:				
								Invoice Cost	(WAC) (\$)	\$42.83	Whsl. Code	#:			
											Fineline Co				
								As of date:							
<u> </u>								11			1				
		_	Attach copy of SAFETY D	ATA SHEET (SDS	i) or non haza		ERT, LABEL AND PHOTO OF I	PRODUCT PACK							
*Please provide any additional inf	formation on page	2.				See new p. 3 for Des	gnated Drop Ship Only.		Signature:						