

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

Version 2021						Introduction 1	Туре:	New Item		x	Final Version			Date:	11/15	5/2022	
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOP	RAGE REQUII	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.												
	xpplication Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 213949 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applicab										•	0						
DUNS:	82-677-4775									Other Ten	nperature Range F	Requirement					
Proprietary Name (If Applicable) ar		ne: Lam	otrigine Extended-Release Tal	blets USP 100m	ng 30ct					(writ	e in)						
	31722-242-30		Unit of Use NDC:			UPC:	33172224	12301		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Oral Solid - Tablet,	Round, biconvex	, film-coated tablets, Orange, U	Jpper: Printed w	ith "Y33" in bla	ck ink Lower: No ma	nark					to customers on i			No		
Active Ingredient(s): Lamotrigine									duct to be shipped	I to customers on o	dry ice?		No				
Active ingredient(s).								b. Contact for	temperatu	ire excursion que	estions:						
URL for Additional Product Information	ation:	www.camberp	harma.com							Name:			Soma Raju				
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			Number:				732-529-0423					
City:		Piscataway State: NJ					Zip: 08854			Group E-mail:				somaraju@heterousa.com			
,	Customer Service 1-866-827-3647				Email: Fax:		customerservice@camberpharma.com 732-562-8788								N.	1	
Phone Number: Product Therapeutic Classification		Anticonvulsant Fax			Fax:	Fax: 732-502-6766			c. Special regulations for product in any states? Special returns requirements for this product?				, No No				
Product Therapeutic Classification		Anticonvulsant								Special re	tums requirement	s for this product?			INO		
	ADDITIO	NAL PRODUCT				PRODUCT	DESCRIPT	ION INFORMATION	d. Store produ	ict (unit of	sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship C	Dnlv						roduct (unit of sa	le) from light?			No	1	
a legend device?	Π	No	Is the Product	Neither		0.	30	ct	e. Shelf life:	oteot p		.c, oin ngitti			24	Months	
if yes, enter class #			Orphan Drug Status			Size:				Initial she	elf life at launch (i	f different):				Months	
a product kit?		No				Strength:	10	0mg			-	-					
if yes, list NDCs of			FDA Approval Status			ou chigan.						ORDER INFORM	MATION				
component parts reverse numbered?						Dosage Form	m: Or	al Solid - Tablet					What is the	NDC selling			
co-licensed?		No No	Allergens Present							Unit of Sa	Bottle		1 bottle of 30		unitr		
latex-free?		No	Allergens riesent				R	ound, biconvex, film-coat			Box/Carton			g. 1 Box of 10) Vials)		
preservative-free?		No				Product Sha	ape:	, , , , , , , , , , , , , , , , , , , ,			Ampule		(g	,		
correctional institution block?		No				Product Col	Or Or	ange			Glass		Minimum or	der quantity	?	Yes	
opioid?		No				i roudet oor					Tube						
Cannabinoid?		No	Country of Origin	China		Product Imp	orint: Up	oper: Printed with "Y33" in			Vial Liquid Sgl		W. V		-1		
If Unit Dose, is item bar coded to un hospital scanning?		No	Is this product covered u	under the							Vial Liquid Multi Vial Powder Sql			many of whi Each	сп раскаде	type?	
If Unit Dose, indicate NDC here:	-		Trade Agreements Act (No						Vial Power Multi		24	Inner/Carton	/Pack		
	L			,							Other: Write In			Case			
-			FOR GENERIC DRUG PR	ODUCTS										4			
									·	L							
					A	uthorized Generic		ized Generic, other				ARMACY ORDER					
	AB						section fie	elds are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: LAMICTAL XL						Each											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g. 1 Vial) Gram											
DRUG SUFFET CHAIN SECURITIACT (DECSA) INFORMATION																	
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0331722000000								ITEM AND PACKING INFORMATION									
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:						Weight Lbs.		ions (US msn	-	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?	-		No		K	nininal una duar	where a		Item/Each:			Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	exclusive distribute	or?	Yes	_	If yes, was o direct from n	riginal product pur	cnased		item/Each:		0.1		1.5	3.25	0	1	
Has FDA granted waiver/exception			No	-		ce manufacturer fo	or repackag	ged product	Box/Carton/B	undle/					0		
If yes, attach documentation from									Inner Pack:						0		
									Case:		2.9	12	9	4	432	24	
		G	TIN AND HIBCC PRODUCT I	NFORMATION					Dellar		-						
Saleable Unit of Measure	Sal	leable Quantity	HIBCC		GT	IN-14		Jnit of Use GTIN-14	Pallet:						0		
x Item/Each	34	1				331722242301		0331722242308	L								
Box/Carton/Bundle/Inner Pack									COST	INFORMATION			WHOLESALI	ER USE ONL	Y:		
X Case		24			103	31722242308											
Pallet	, .						_		Regular Cost				Vendor #:				
							_		Invoice Cost (WAC) (\$)		\$45.11	Whsl. Code				
							-		As of date:	E			Fineline Co	ue:			
							-		, is of date.								
	. L						_										
·			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE	E INSERT, I	LABEL AND PHOTO OF P	RODUCT PACKA	GING and	BARCODE.		•				
*Please provide any additional info	ormation on page 2.	-						ed Drop Ship Only.		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? No (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: Image: Contact Hazard NFPA Storage Level: Image: Contact Hazard 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 Listed Chemical (List I or II) No ARCOS Reportable? Is it a scheduled listed chemical product?: No Controlled Substance Code Controlled Substance Code Listed Chemical (List I or II) No Controlled Substance Code Listed Chemical (List I or II) No Controlled Substance Code Controlled Subst	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes						
CLASS OF TRADE RESTRICTION: 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	URL/Link to returns policy: contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
Comments: MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						



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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?