

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

Version 2021						Introduction T	ype:	New Item	x	Final Version			Date:	6/23/	2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	AGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AND	Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215259 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applicable:															
	11-856-3719									mperature Range F	Requirement	Excursions a	llowed betwe	en 15° and 3	0°C (59°
Proprietary Name (If Applicable) and	nd Established Name	e: Levothy	roxine Sodium Tablets, US							ite in)		and 86°F)			
5	31722-293-10		Unit of Use NDC:			UPC:	33171222	93105	Notes						
UDI			CVX Code:			MVX Code:									
Description:	Levothyroxine Sodiur	m Tablets, USP 17	5 mcg							oduct to be shipped				No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Levothyroxine sodium, USP b. Contact for temperature excursion questions:															
URL for Additional Product Inform	for Additional Product Information:								Name:	ture excursion que	estions:	Soma Raju			
		800 Centennial Ave, Suite 1				Address 2:			Number	732-529-0423					
	Piscataway State:			NJ				-mail:			omaraju@heterousa.com				
	Customer Service				customerservice	stomerservice@camberpharma.com						_			
Phone Number:	1-866-827-3647				732-562-8788			c. Special regulations for product in any states? No							
Product Therapeutic Classification	n: S	ynthetic thyroid hor	mone				Special returns requirements for this product?					No			
	ADDITION	AL PRODUCT INF				PRODUCT I	DESCRIPTI	ON INFORMATION	d. Store product (unit o					No	
The product is?			Is the Product	Direct-Ship O	nly					product (unit of sa	le) from light?			No	
a legend device?	N	lo	Is the Product	Neither		Size:	100	00 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status				470		Initial sh	elf life at launch (i	f different):				Months
a product kit? if yes, list NDCs of	N	10	FDA Approval Status			Strength:	1/5	5 mcg			ORDER INFORM				
component parts							Tab	olet			ORDER IN OR				
reverse numbered?	N	lo				Dosage Form	n:		Unit of S	ale		What is the	NDC selling	unit?	
co-licensed?	N		Allergens Present						x	Bottle		1 Bottle of 10	000 Tablets		
latex-free?	Y	es	Alcohol	Sugar, Dye		Product Sha	Cap	psule, biconvex		Box/Carton		(Write-in, e.g	g. 1 Box of 10	) Vials)	
preservative-free?	N		Alconol,	ougui, byc		i roduct ona				Ampule					
correctional institution block?	N					Product Cold	or: Lila	iC		Glass		Minimum or	der quantity	?	Yes
opioid?	N		Country of Origin	USA			Plain	on one side and debossed '1		Tube					
Cannabinoid? If Unit Dose, is item bar coded to un	N nit doop for	0	Country of Origin	USA		Product Imp	rint: score	e line 0' on the other side		Vial Liquid Sgl Vial Liquid Multi		If Yes, how i	many of whi	ch nackado t	wno?
hospital scanning?	nit dose toi		Is this product covered u	inder the						Vial Powder Sql			Each	un package i	ype:
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes				Vial Powder Multi Inner/Carton/Pack						
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
										1		_			
					Αι	uthorized Generic		zed Generic, other			ARMACY ORDER	/ BILL UNIT			
	AB4						section fie	lds are not applicable	Rec. sell unit to custon	ner?		Rx billing ur		icy:	
II. Generic Equivalent to What Brand?: Thyro-Tabs								Each							
			Y CHAIN SECURITY ACT (		MATION				(Write-in, e.g. 1 Vial)				Gram Milliliter		
		DR00 S0FFE	I CHAIN SECONT I ACT (	DSCSA) IN ON									winning		
Does supplier meet DSCSA definit	ion of manufacturer	?	Yes		GLN:	0331722498975				ITEM	AND PACKING I	NFORMATION			
Is product exempt from DSCSA?			No	-											
If yes, select exemption:					GCP:						Dimensi	ons (US msm	ts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product pure	chased		Item/Each:	0.34	2.25	2.25	4.25	21.52	1
Is product sold by manufacturer's			Yes		direct from n					0.34	2.25	2.25	4.20	21.02	
Has FDA granted waiver/exception		uct?	No		Provide sour	rce manufacturer fo	or repackag	ed product	Box/Carton/Bundle/						
If yes, attach documentation from	n FDA.								Inner Pack:						
		GTIN	I AND HIBCC PRODUCT I	NEORMATION					Case:	8.55	14.5	10	5	725	24
									Pallet:						
Saleable Unit of Measure	Sale	able Quantity	HIBCC		GT	IN-14	U	nit of Use GTIN-14							
X Item/Each		1			003	331722293105									
Box/Carton/Bundle/Inner Pack									COS	T INFORMATION		1	NHOLESALE	ER USE ONL	Y:
X Case		24			103	331722293102									
Pallet							-		Regular Cost			Vendor #:	<i>u</i> .		
	-						-		Invoice Cost (WAC) (\$)		\$233.11	Whsl. Code Fineline Cod			
	-				-				As of date:	3/13/2023		i menne coo			
												1			
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE	INSERT, L	ABEL AND PHOTO OF P	RODUCT PACKAGING and	BARCODE.					
*Please provide any additional info	ormation on page 2.							d Drop Ship Only.	Signatur						

## HDA🔾

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

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3								
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION								
Is this product (check all that apply): a. Cytotoxic? 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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Is the product a NIOSH hazardous drug?         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       If yes, indicate which:							
a. On/definition for holder     b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group     e. Inhalation Hazard?     Is this product regulated for shipment by IATA?     No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:							
(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?	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:           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) Special Permit; DOT-SP	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       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	No       Registry Program Contact Name:       Comments							
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	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	URL/Link to returns policy: contact - customerservice@camberpharma.com							
No     No       Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?							
MISCELLANE	OUS 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?