

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

Version 2021						Introduction	Туре:	New Item		x	Final Version			Date:	4/5/2	2023
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals. Inc.					Applica	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.				ct.			
Application Number for NDA/ANI			ce):	21	5259							Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab		~								·	Ū					
DUNS:	82-677-4775									Other Te	mperature Range R	Requirement				
Proprietary Name (If Applicable) a		Levoth	nyroxine Sodium Tablets US	P, 137mcg					Ι	(wri	te in)					
Selling Unit NDC:	31722-291-10		Unit of Use NDC:			UPC:	331722	291101		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Levothyroxine Sodium Ta	blets USP, 13	37mcg						Ī	Is this pro	duct to be shipped	to customers on i	ce?		No	
Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Levothyroxine Sodium b. Contact for temperature excursion questions:																
URL for Additional Product Inform										temperat Name:	ure excursion que	estions:	Come Deiu			
Address:	ation: www.camberpharma.com 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			Number:				Soma Raju 732-529-042	2			
City:	Piscataway State:				NJ Zip: 08854			Group E-mail:					.o neterousa.cor	n		
Key Contact:	Customer Service						customerservice@camberpharma.com								-	
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	ulations f	or product in any	states?			No	
Product Therapeutic Classification	n: Synth	etic Thyroid H	lormone							Special r	eturns requirements	s for this product?			No	
	ADDITIONAL F	PRODUCT IN	FORMATION			PRODUCT	DESCRIP	PTION INFORMATION	d. Store produ	ict (unit c	f sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Dnly					Protect p	roduct (unit of sa	le) from light?			No	
a legend device?	No		Is the Product	Neither		Size:	1	1000ct	e. Shelf life:	-					24	Months
if yes, enter class #			Orphan Drug Status			0120.	_			Initial sh	elf life at launch (i	f different):				Months
a product kit?	No					Strength:	1	137mcg								
if yes, list NDCs of component parts			FDA Approval Status			-		Tablet				ORDER INFORM	ATION			
reverse numbered?	No					Dosage For	m:	abiel		Unit of S	alo		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present								Bottle		1 bottle of 10			
latex-free?	Yes		g			Bas days of	c	capsule shaped, biconvex			Box/Carton			g. 1 Box of 10	) Vials)	
preservative-free?	No					Product Sha		tablets			Ampule			•		
correctional institution block?	No					Product Col	lor. 1	Turquoise			Glass		Minimum or	der quantity	?	Yes
opioid?	No										Tube					
Cannabinoid?	No		Country of Origin	USA		Product Imp		plain on one side and debossed "score line 8"			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	nit dose for		Is this product covered u	under the				on the other side.			Vial Liquid Multi Vial Powder Sql			many of whi Each	ch package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes			on the other side.			Vial Power Multi			Inner/Carton	/Pack	
il offit bose, indicate rubo nere.					103						Other: Write In			Case	1 dok	
			FOR GENERIC DRUG PR	ODUCTS					<u> </u>					1		
					A	uthorized Generic		orized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4						section	fields are not applicable	Rec. sell unit	o custon	ier?		Rx billing u	nit to pharma	ncy:	
II. Generic Equivalent to What Brand?: Thyro-Tabs								Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial) Gram									
		ROG SUPPL	LT CHAIN SECURITY ACT (	USCSA) INFOR	RMATION				_					Milliliter		
Does supplier meet DSCSA definit	tion of manufacturer?		Yes		GLN:	0331722000000					ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No	-												
If yes, select exemption:					GCP:				i l			Dimensi	ons (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									1		Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product pur	rchased		Item/Each:		0.33	2.25	2.25	4.25	21.52	1
Is product sold by manufacturer's			Yes		direct from n	nfr?					0.33	2.20	2.20	4.20	21.02	
Has FDA granted waiver/exception			No		Provide sour	rce manufacturer fo	or repack	aged product	Box/Carton/Bu	undle/						
If yes, attach documentation from	n FDA.								Inner Pack:							
		GTI	N AND HIBCC PRODUCT I	NEORMATION					Case:		8.45	14.5	10	5	725	24
									Pallet:							
Saleable Unit of Measure	Saleable	Quantity	HIBCC		GT	IN-14		Unit of Use GTIN-14								
X Item/Each						331722291101										
Box/Carton/Bundle/Inner Pack										COS	INFORMATION			WHOLESALI	ER USE ONL	Y:
X Case	2	4			103	331722291108	_									
Pallet							_		Regular Cost				Vendor #:			
	-				-		-		Invoice Cost (	WAC) (\$)		\$154.44	Whsl. Code Fineline Co			
	-						-		As of date:		4/5/2023		Theme Co	u <del>c</del> .		
							-		Als of date.				1			
l'			Attach copy of SAFETY DA	ATA SHEET (SD	OS) or non haza	ard letter, PACKAGE	E INSERT	, LABEL AND PHOTO OF P	PRODUCT PACKA	GING and	BARCODE.					
*Please provide any additional info	ormation on page 2.			- (				ated Drop Ship Only.		Signatur						

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

Version 2021 For Des	signated Drop Ship Only Products, Please Use Page 3						
MATERIA	L HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? N b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? N Is the product a CA Prop 65 reproductive toxicant? N 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? N	x       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Contact Hazard						
e. Does the product contain DET if it is product regulated for shipment by DOT? Is this product regulated for shipment by DOT? (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?	o         EPA Hazardous Waste Code:         Waste Characteristics						
Is this product regulated for shipment by IATA? (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 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:          N         Passenger         Cargo         Passenger & Cargo	o     Med Guide Required     No       Limited Distribution Requirement     Image: Comments / Details: (For example, iPledge program?)     Image: Comment of the second secon						
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:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Parister No.						
SP#ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION: No No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerservice@camberpharma.com						
No resultation: seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices     If the second seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices       Restricted to retail pharmacy only:     N       Restricted to hospital, clinics, and physician offices only:     N       Restricted from US territories? (explain in comments)     N       Comments:     Image: Comment in the second se	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCEL	ANEOUS 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?