

## **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 INFORM	ATION						SPECIAL HAN	DLING AND STOP	AGE REQUIR	EMENTS*		
Company Name: Camber Pharmaceuticals. Inc.				Applica	ation:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANI			21	5259					rature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	82-677-4775							Other T	emperature Range F	Requirement				
Proprietary Name (If Applicable) and	nd Established Name:	Levothyroxine Sodium Tablets US						(v	vrite in)					
Selling Unit NDC:	31722-295-90	Unit of Use NDC	:	31722-295-90		3317222959	01	Notes						
UDI		CVX Code:			MVX Code:			·						
Description:	Levothyroxine Sodium Tablet	ts USP, 300mcg						Is this p	product 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														
URL for Additional Product Information: www.camberpharma.com b. Contact for temperature excursion questions: Name: Soma Raju														
Address:		berpharma.com			Address 2:			Name: Numbe	<b></b>		Soma Raju 732-529-042	3		
City:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 Piscataway State:			N.I	Zip: 088	54	Group E-mail:			somaraju@heterousa.com				
Key Contact:	Customer Service	- iocatana)				@camberpharr							-	
	1-866-827-3647			Fax:	732-562-8788			c. Special regulations	for product in any	states?			No	
Product Therapeutic Classification	n: Synthetic	Thyroid Hormone						Special	returns requirement	s for this product?			No	
				_										
	ADDITIONAL PRO	DDUCT INFORMATION			PRODUCT	DESCRIPTION	N INFORMATION	d. Store product (unit	of sale) upright?				No	
The product is?		Is the Product	Direct-Ship (	Dnly				Protect	product (unit of sa	le) from light?			No	
a legend device?	No	Is the Product	Unit of Use		Size:	90ct		e. Shelf life:					24	Months
if yes, enter class #		Orphan Drug Status			0120.			Initial s	shelf life at launch (i	f different):				Months
a product kit?	No				Strength:	300m	ncg							
if yes, list NDCs of component parts		FDA Approval Status				Table	×+			ORDER INFORM	ATION			
reverse numbered?	No	_			Dosage For	m:	51	Unit of	Sale		What is the I	NDC selling	unit?	
co-licensed?	No	Allergens Present						x	Bottle		1 bottle of 90			
latex-free?	Yes				Desident Of	capsu	ule shaped, biconvex		Box/Carton		(Write-in, e.g		) Vials)	
preservative-free?	No	_			Product Sha	tablet			Ampule					
correctional institution block?	No				Product Col	Green	n		Glass		Minimum or	der quantity	?	Yes
opioid?	No				i iouuci ooi				Tube					
Cannabinoid?	No	Country of Origin	USA		Product Imp		on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for	Is this product covered					ssed "1 score line 2" e other side.		Vial Liquid Multi Vial Powder Sql		If Yes, how r 24	nany of white Each	ch package t	ype?
If Unit Dose, indicate NDC here:		Trade Agreements Act		Yes		on the	e outer side.		Vial Power Multi			Each Inner/Carton	/Pack	
in Onit Dose, indicate NDC here.		Thate Agreements Act	(1704):	163					Other: Write In			Case	1 dok	
		FOR GENERIC DRUG P	RODUCTS											
				Au	thorized Generic		d Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4					section fields	s are not applicable	Rec. sell unit to custo	omer?		Rx billing ur	it to pharma	icy:	
II. Generic Equivalent to What Brand?: Thyro-Tabs							Each							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial) Gram							
	DRU	JG SUPPLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION								Milliliter		
Does supplier meet DSCSA definit	ion of manufacturer?	Yes		GLN:	0331722000000				ITEN	I AND PACKING II	NFORMATION			
Is product exempt from DSCSA?		No	_	02.11	0001122000000									
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 or	iginal product pur	rchased		Item/Each:	0.083	1.5	1.5	3	6.75	1
Is product sold by manufacturer's	exclusive distributor?	Yes		direct from m					0.063	1.5	1.5	3	0.75	1
Has FDA granted waiver/exception		No		Provide source	ce manufacturer fo	or repackaged	d product	Box/Carton/Bundle/						
If yes, attach documentation from	n FDA.							Inner Pack:						
		GTIN AND HIBCC PRODUCT						Case:	2.35	10	7	4.25	297.5	24
		GTIN AND HIBCC PRODUCT	INFORMATION					Pallet:						
Saleable Unit of Measure	Saleable Qu	antity HIBCC		GTI	N-14	Unit	t of Use GTIN-14	i unct.						
X Item/Each	1				31722295901		31722295901							
Box/Carton/Bundle/Inner Pack								CO	ST INFORMATION		1	WHOLESALE	ER USE ONL	Y:
X Case	24			103	31722295908	_								
Pallet				_		-		Regular Cost			Vendor #:			
	-					_		Invoice Cost (WAC) (\$	5)	\$24.74	Whsl. Code			
	-	_				-		As of date:	4/5/2023		Fineline Coo	ie:		
						-		As of udie.						
L.		Attach copy of SAFETY D	ATA SHEET (SI	OS) or non haza	rd letter, PACKAGE	E INSERT, LAE	BEL AND PHOTO OF P	RODUCT PACKAGING a	nd BARCODE.		•			
*Please provide any additional info	ormation on page 2.			_,	See new p. 3 for			Signati						

## **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:           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 source retail pharmacy, nospitals, cuinces and physician offices     If the second seed Yes if source retail 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: Comments in the second s	O     Special regulations or returns requirements for this       o     product in certain states?						
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?