

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

						Introduction Type:	New Item		x Final Version			Date:	4/5/	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatu	ure - Indicate the USP temp	erature range for th	is product.			
Application Number for NDA/AN	IDA/BLA (drug); PN	IA/510(k)(med device	ce):	21	5259		1	11	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	82-677-4775							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Levoth	hyroxine Sodium Tablets US						(write in)					
Selling Unit NDC:	31722-287-10		Unit of Use NDC:				22287104	<b>↓</b>	Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Levothyroxine Soc	dium Tablets USP, 88	8mcg					T	Is this product to be shippe	d to customers on ic	e?		No	
								1	Is this product to be shipped	d to customers on d	y ice?		No	
Active Ingredient(s):		Levothyroxine Sodi	um					11		_				
URL for Additional Product Inform								b. Contact fo	or temperature excursion qu	estions:	Soma Raju			
Address:		www.camberpharma				Address 2:		+	Name: Number:		732-529-042	2		
City:	Piscataway	ve (and) 000 Center	illiai Ave, Suite 1		State:		: 08854	-	Group E-mail:		somaraju@h		<u> </u>	
Key Contact:	Customer Service				Email:	customerservice@cam		-	o.oup 2 main		<u>oomaraja on</u>	01010404.001	<u>.</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	gulations for product in any	states?			No	
Product Therapeutic Classificatio	n:	Synthetic Thyroid H	formone					- I	Special returns requirement				No	
-					_					•				1
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only			11	Protect product (unit of sa	le) from light?			No	ĺ
a legend device?		No	Is the Product	Neither	-	Cine.	1000ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	88mcg							
if yes, list NDCs of			FDA Approval Status			Ou engui.				ORDER INFORM	ATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No	All B			-			Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				capsule shaped, biconvex		x Bottle Box/Carton		1 bottle of 10 (Write-in, e.g		\ \/iolo\	
preservative-free?		No				Product Shape:	tablets		Ampule		(**************************************	j. 1 DOX 01 10	, viais)	
correctional institution block?		No					Olive		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube			,	-	
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	plain on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					Product imprint.	one side and debossed		Vial Liquid Multi		If Yes, how		ch package t	ype?
hospital scanning?		No	Is this product covered u				"score line 4" on the other		Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	Yes		side.		Vial Power Multi			Inner/Carton	/Pack	
								<u>J</u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
							uthorized Generic, other			ARMACY ORDER				
I Ocean are Developed to an	AD4				Au			Boo coll unit		ARMACT ORDER				
I. Orange Book Rating:	AB4	Thuro-Tabe			Au		on fields are not applicable	Rec. sell unit	t to customer?	ARMACT ORDER	Rx billing ur		icy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Thyro-Tabs			Au				t to customer?	ARMACT ORDER		Each	ісу:	
			.Y CHAIN SECURITY ACT (	(DSCSA) INFOR				Rec. sell unit	t to customer?	ARWACT ORDER			icy:	
			LY CHAIN SECURITY ACT (	(DSCSA) INFOR					t to customer? g. 1 Vial)		Rx billing ur	Each Gram Milliliter	ісу:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini	and?:	DRUG SUPPL	Yes	(DSCSA) INFOR					t to customer? g. 1 Vial)	I AND PACKING IN	Rx billing ur	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL		(DSCSA) INFOR	RMATION	secti			t to customer? g. 1 Vial)		Rx billing ur	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption:	and?:	DRUG SUPPL	Yes	(DSCSA) INFOR	RMATION	secti			t to customer? g. 1 Vial)	I AND PACKING IN	Rx billing ur	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPPL	Yes No	(DSCSA) INFOR	RMATION GLN:	secti		(Write-in, e.g	t to customer? g. 1 Vial)	I AND PACKING IN	Rx billing ur	Each Gram Milliliter		Saleable #
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	AZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive 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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:					
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  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)	REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  No  Phone:  DEA #:  NCPDP#:  NCPDP#:  NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments					
Is the Product	RETURN INSTRUCTIONS					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No.  No CLASS OF TRADE RESTRICTION:  Controlled Substance Code Listed Chemical (List I or II) No No State Chemical (List I or II) No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments)  Comments:	If so, which states? Other requirements? Comments?					
MISCELLAI	IEOUS 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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? Is product order for restocking purposes?