

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

						Introduction	Type: New Item		x Final Version			Date:	6/23/	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Applica	tion: ANDA	a. Temperat	ure - Indicate the USP tempe	rature range for th	is product.			
Application Number for NDA/AN	IDA/BLA (drug); PN	IA/510(k)(med device	ce):	215	5259				Temperature Range	Controlled Room -	between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applica	ble:													
DUNS:	11-856-3719								Other Temperature Range F	equirement	Excursions a	llowed betwe	en 15° and 3	0°C (59°
Proprietary Name (If Applicable) a		me: Levoth	nyroxine Sodium Tablets, US						(write in)		and 86°F)			
Selling Unit NDC:	31722-292-10		Unit of Use NDC:			UPC:	331722292108		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Levothyroxine Soc	dium Tablets, USP 15	50 mcg						Is this product to be shipped	to customers on ic	e?		No	
									Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		Levothyroxine sodiu	um, USP											
UDI for Additional Brades Inform								b. Contact fo	or temperature excursion que	stions:	O D - '			
URL for Additional Product Inform Address:	800 Centennial Av	www.camberpharma	a.com		ı	Address 2:			Name: Number:		Soma Raju 732-529-042	n		
City:	Piscataway	re, Suite i			State:	NJ	<b>Zip</b> : 08854	_	Group E-mail:				^	
Key Contact:	Customer Service					@camberpharma.com		Group E-mail: somaraju@heterousa.com			Ц			
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any	states?			No	]
Product Therapeutic Classification	on:	Synthetic thyroid ho	ormone		1				Special returns requirements				No	
·					1									ı
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store pro	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of sa	e) from light?			No	Ī
a legend device?		No	Is the Product	Neither		Ci	1000 ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (i	different):				Months
a product kit?		No				Strength:	150 mcg							
if yes, list NDCs of			FDA Approval Status			ou engui.				ORDER INFORM	ATION			
component parts						Dosage For	m: Tablet		Hely of Oak		\A/lagt !a tha	NDC aalliaa		
reverse numbered? co-licensed?		No No	Allergens Present						Unit of Sale x Bottle		What is the 1 Bottle of 10		unitr	
latex-free?		Yes					Capsule, biconvex		Box/Carton		(Write-in, e.		) Vials)	
preservative-free?		No	Alcohol,	Sugar, Dye		Product Sha	pe:		Ampule		(	,	- 1,	
correctional institution block?		No				Product Col	Blue		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Col	or.		Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imp	rint: Plain on one side and debossed 'score line 9' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						Societing of artific duter side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered to Trade Agreements Act (		Vaa				Vial Powder Sgl Vial Powder Multi			Each	/Deals	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)!	Yes				Other: Write In			Inner/Carton Case	Pack	
									Other. Write in					
			FOR GENERIC DRUG PR	PODUCTS										
			FOR GENERIC DRUG PR	ODUCTS										
			FOR GENERIC DRUG PR	RODUCTS	Au	uthorized Generic	*If Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4		FOR GENERIC DRUG PR	RODUCTS	Au	uthorized Generic	*If Authorized Generic, other section fields are not applicable	Rec. sell uni	PH it to customer?	ARMACY ORDER		nit to pharma	acv:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Thyro-Tabs	FOR GENERIC DRUG PR	RODUCTS	Au	uthorized Generic		Rec. sell uni		ARMACY ORDER	/ BILL UNIT Rx billing u	nit to pharma	асу:	
						uthorized Generic		Rec. sell uni	it to customer?	ARMACY ORDER		Each Gram	асу:	
			FOR GENERIC DRUG PR			uthorized Generic			it to customer?	ARMACY ORDER		Each	асу:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				it to customer? g. 1 Vial)		Rx billing u	Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra	and?: ition of manufacture	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR		uthorized Generic			it to customer? g. 1 Vial)	ARMACY ORDER	Rx billing u	Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?: ition of manufacture	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION GLN:				it to customer? g. 1 Vial)	AND PACKING IN	Rx billing un	Each Gram Milliliter		Salashia "
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption:	and?: ition of manufacture	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				it to customer? g. 1 Vial)	AND PACKING IN	Rx billing un	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?: ition of manufacture	DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	GLN:	0331722498975	section fields are not applicable	(Write-in, e.s	it to customer? g. 1 Vial) ITEM Weight Lbs.	AND PACKING IN Dimensie Depth	Rx billing un  FORMATION  Ons (US msm  Width	Each Gram Milliliter ts.)	Volume (Cube)	Pieces
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption:	and?: ition of manufacture	DRUG SUPPL	Y CHAIN SECURITY ACT ( Yes No	(DSCSA) INFOR	GLN:	0331722498975	section fields are not applicable		it to customer? g. 1 Vial)	AND PACKING IN	Rx billing un	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: ition of manufactur	DRUG SUPPL	Y CHAIN SECURITY ACT  Yes  No	(DSCSA) INFOR	GLN: GCP: If yes, was oldirect from n	0331722498975	section fields are not applicable	(Write-in, e.s.	g. 1 Vial)  TEM  Weight Lbs.  0.34	AND PACKING IN Dimensie Depth	Rx billing un  FORMATION  Ons (US msm  Width	Each Gram Milliliter ts.)	Volume (Cube)	Pieces
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II. Generic Equivalent to What Bra  Does supplier meet DSCSA definition is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation fro  Saleable Unit of Measure  X Item/Each	and?: ition of manufactur s exclusive distribu on/exemption for pro	DRUG SUPPL er? tor? oduct? GTI	Yes No  No Yes No No And Hiboc Product I	(DSCSA) INFOR	GLN: GCP: If yes, was ordirect from n Provide sour	0331722498975 riginal product pur ffr? ce manufacturer fo	section fields are not applicable	Item/Each: Box/Carton/Inner Pack: Case:	it to customer? g. 1 Vial)  ITEM  Weight Lbs.  0.34  Bundle/  8.55	AND PACKING IN Dimension Depth 2.25	Rx billing unline (IFORMATION) ons (US msm Width 2.25	Each Gram Milliliter ts.) Height 4.25	Volume (Cube) 21.52 725	Pieces 1 24
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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 HA	ZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic?  No	SDS Hazard Classification				
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?  No  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?	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#:  NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments				
ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:				
Is the Product					
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  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)  No  Comments:	If so, which states? Other requirements? Comments?				
MISCELLANE	DUS 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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process 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?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?