

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

						Introduction Type:	New Item		x Final Version			Date:	5/4/	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			ce):	21	5259			1	Temperature Range	Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical		. , ,	•											
DUNS:	11-856-3719							_	Other Temperature Range I	Requirement	Excursions a	llowed between	en 15° and 3	30°C (59°
Proprietary Name (If Applicable) a	and Established Na	me: Levoth	hyroxine Sodium Tablets, US	SP 25 mcg				T	(write in)	·	and 86°F)			
Selling Unit NDC:	31722-284-10		Unit of Use NDC			UPC: 3317	22284103	1	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Levothyroxine Soc	dium Tablets, USP 2	5 mca					П	Is this product to be shipped	to customers on ic	e?		No	1
			9						Is this product to be shipped				No	1
Active Ingredient(s):		Levothyroxine sodi	um, USP								•			4
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inforn	mation:	www.camberpharma	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	re, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>m</u>	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com							7
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any				No	-
Product Therapeutic Classificatio	on:	Synthetic thyroid ho	ormone						Special returns requirement	s for this product?			No	_
	A DOITH	ONAL PROPUST IN	FORMATION			PROPUST RESS	DIDTION INFORMATION	-						7
	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				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (if different):				Months
a product kit?		No	EDA 4			Strength:	25 mcg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Tablet			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 10		uiii.	
latex-free?		Yes	_				Capsule, biconvex		Box/Carton		(Write-in, e.g		0 Vials)	
preservative-free?		No	Alcohol,	Sugar, Dye		Product Shape:			Ampule		, , , ,	,	,	
correctional institution block?		No				Product Color:	Orange		Glass		Minimum or	der quantity	<i>i</i> ?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	Plain on one side and debossed 'score line 1' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					r roduct imprint.	score line 1° on the other side		Vial Liquid Multi		If Yes, how I		ich package	type?
hospital scanning?			Is this product covered						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:														
			Trade Agreements Act (TAA)?	Yes				Vial Powder Multi			Inner/Cartor	n/Pack	
				• •	Yes				Other: Write In			Inner/Cartor Case	n/Pack	
			FOR GENERIC DRUG PR	• •	Yes								n/Pack	
				• •					Other: Write In				n/Pack	
				• •			uthorized Generic, other		Other: Write In	ARMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating:	AB4			• •			uthorized Generic, other on fields are not applicable	Rec. sell unit	Other: Write In	ARMACY ORDER		Case		
I. Orange Book Rating: II. Generic Equivalent to What Bra		Thyro-Tabs		• •					Other: Write In PH t to customer?	ARMACY ORDER	/ BILL UNIT	case it to pharmates		
			FOR GENERIC DRUG PF	RODUCTS	Au			Rec. sell unit	Other: Write In PH t to customer?	ARMACY ORDER	/ BILL UNIT	case it to pharm Each Gram		
				RODUCTS	Au				Other: Write In PH t to customer?	ARMACY ORDER	/ BILL UNIT	case it to pharmates		
II. Generic Equivalent to What Bra	and?:	DRUG SUPPI	FOR GENERIC DRUG PF	RODUCTS	Au	sect			Other: Write In Pt to customer? 1. 1 Vial)		/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter		
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini	and?:	DRUG SUPPI	FOR GENERIC DRUG PF	RODUCTS	Au				Other: Write In Pt to customer? 1. 1 Vial)	ARMACY ORDER	/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter		
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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 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?