

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

Version 2021						Introduction 1	Туре:	New Item	X	Final Version			Date:	6/23/	2024
		PRODI	UCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Applica	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
	IDA/ANDA/BLA (drug); PMA/510(k)(med device): 215259							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:															
DUNS:	11-856-3719								Other 1	emperature Range I	Requirement	Excursions a	llowed betwe	en 15° and 3	0°C (59°
Proprietary Name (If Applicable) and		Levothyroxine Sodi				1				vrite in)		and 86°F)			
5	31722-289-90		hit of Use NDC:		31722-289-90		33172	2289900	Notes						
UDI		C	VX Code:			MVX Code:									
Description:	Levothyroxine Sodium Table	ts, USP 112 mcg								product to be shipped				No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Levothyroxine sodium, USP b. Contact for temperature excursion questions:															
URL for Additional Product Inform	ation: www.cam	bernharma com							b. Contact for temper Name:	ature excursion qu	estions:	Soma Raju			
Address:	800 Centennial Ave, Suite 1					Address 2:			Number: 732-529-0423						
					NJ	Zip:	08854	Group E-mail: somaraju@heterousa.com				n			
	Customer Service					customerservice							_		
Phone Number:	1-866-827-3647					732-562-8788			c. Special regulations for product in any states? No						
Product Therapeutic Classification	n: Synthetic	Synthetic thyroid hormone							Specia	returns requirement	s for this product?			No	
					_										
	ADDITIONAL PRC	DUCT INFORMATION	N			PRODUCT	DESCRI	IPTION INFORMATION	d. Store product (unit	of sale) upright?				No	
The product is?		Is the Pr	oduct	Direct-Ship C	Only	1			Protec	product (unit of sa	le) from light?			No	
a legend device?	No	Is the Pr		Unit of Use		Size:		90 ct	e. Shelf life:					24	Months
if yes, enter class #		Orphan I	Drug Status			0.20.			Initial	shelf life at launch (if different):				Months
a product kit?	No					Strength:		112 mcg							
if yes, list NDCs of component parts		FDA App	proval Status			-		Tablet			ORDER INFORM	IATION			
reverse numbered?	No	_				Dosage Form	m:	I ablet	Unit of	Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergen	s Present						x	Bottle		1 Bottle of 90			
latex-free?	Yes			0 D		Barrier Ola		Capsule, biconvex		Box/Carton		(Write-in, e.g) Vials)	
preservative-free?	No		Alconol,	Sugar, Dye		Product Sha	ape:			Ampule				,	
correctional institution block?	No					Product Col	or	Rose		Glass		Minimum or	der quantity	?	Yes
opioid?	No					i iouuci ooi	01.			Tube					
Cannabinoid?	No	Country of	of Origin	USA		Product Imp	orint:	Plain on one side and debossed 'score line 6' on the other side		Vial Liquid Sgl					-
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for	la thia an	oduct covered u							Vial Liquid Multi					
If Unit Dose, indicate NDC here:			oduct covered L greements Act (Yes				Vial Powder Sgl 24 Each Vial Powder Multi Inner/Carton/Pack						
in oniti bose, indicate NDC here.		Thate Ag	greements / tot (163					Other: Write In			Case	/i dok	
		FOR GENE	ERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Aut	horized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB4						sectior	n fields are not applicable	Rec. sell unit to custo	omer?		Rx billing ur	nit to pharma	acy:	
II. Generic Equivalent to What Brand?: Thyro-Tabs								Each							
									(Write-in, e.g. 1 Vial)				Gram		
	DRU	JG SUPPLY CHAIN SE	ECURITY ACT ((DSCSA) INFOR	RMATION								Milliliter		
Does supplier meet DSCSA definit	ion of manufacturor?	Ye	e .	_	GLN:	0331722498975				ITEA	I AND PACKING I		J		
Is product exempt from DSCSA definit		No	10		GLN:	0331722496975					FARD FACKING II	- OKMATION			
					GCP:		_				Dimonsi	ons (US msm	te)	Val	Calcality #
If yes, select exemption: Other exemption - Write in:					GUP:					Weight Lbs.		ons (US msm Width	'	Volume (Cube)	Saleable # Pieces
Is product repackaged?		No			If yes was or	iginal product pur	chasod		Item/Each:		Depth		Height		
Is product sold by manufacturer's	exclusive distributor?	Ye	s	-	direct from m		chasea		item/Edon.	0.08	1.5	1.5	3	6.75	1
Has FDA granted waiver/exception		No				ce manufacturer fo	or repac	kaged product	Box/Carton/Bundle/						
If yes, attach documentation from	n FDA.	1							Inner Pack:						
									Case:	2.35	10	7	4.25	297.5	24
-		GTIN AND HIBC	CC PRODUCT I	NFORMATION									-		
Saleable Unit of Measure	Saleable Qu	antity HIBCC			CTU	N-14		Unit of Use GTIN-14	Pallet:						
X Item/Each	Saleable Qu	апшу півсс				31722289900		00331722289900							
Box/Carton/Bundle/Inner Pack		_				01722203300	-	00001122200000	CO	ST INFORMATION			WHOLESALI	ER USE ONL	Y:
X Case	24				103	31722289907	-								
Pallet					-				Regular Cost			Vendor #:			
									Invoice Cost (WAC) (5)	\$14.86	Whsl. Code			
					_							Fineline Coo	de:		
							_		As of date:	3/13/2023					_
<u> </u>		A 1			0)	- Hana Brown		T LADEL AND BUGTO		10400005		L			
*Disess provide one add// ! f-	annation on none 2	Attach copy	y of SAFETY DA	ATA SHEET (SD	ס) or non haza			T, LABEL AND PHOTO OF F							
*Please provide any additional info	ormation on page 2.					See new p. 3 for	r Design	ated Drop Ship Only.	Signat	ure:					

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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 HAZARD CLASSIFICATION and TRANSPORTATION								
Is this product (check all that apply): a. Cytotoxic? 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? 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? No Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:							
a. On/definition for holder b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:							
(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?	REMS or REGISTRY RESTRICTIONS 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	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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:							
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No Registry Program Contact Name: Comments							
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes							
CLASS OF TRADE RESTRICTION: 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: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?							
MISCELLANE	OUS 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?