



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215259
Medical Device Class, if applicable:
DUNS: 82-677-4775
Proprietary Name (If Applicable) and Established Name: Levothyroxine Sodium Tablets USP, 175mcg
Selling Unit NDC: 31722-293-90 **Unit of Use NDC:** 31722-293-90 **UPC:** 331722293907
UDI **CVX Code:** **MXV Code:**
Description: Levothyroxine Sodium Tablets USP, 175mcg
Active Ingredient(s): Levothyroxine Sodium
URL for Additional Product Information: www.camberpharma.com
Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 **Address 2:**
City: Piscataway **State:** NJ **Zip:** 08854
Key Contact: Customer Service **Email:** customerservice@camberpharma.com
Phone Number: 1-866-827-3647 **Fax:** 732-562-8788
Product Therapeutic Classification: Synthetic Thyroid Hormone

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
b. Contact for temperature excursion questions:
Name: Soma Raju
Number: 732-529-0423
Group E-mail: somaraju@heterousa.com
c. Special regulations for product in any states?
 Special returns requirements for this product?
d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?
e. Shelf life: Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="No"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Unit of Use	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text"/>
latex-free?	<input type="text" value="Yes"/>	FDA Approval Status	<input type="text"/>
preservative-free?	<input type="text" value="No"/>	Allergens Present	<input type="text"/>
correctional institution block?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="USA"/>
opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
Cannabinoid?	<input type="text" value="No"/>	Size:	<input type="text" value="90ct"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Strength:	<input type="text" value="175mcg"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="capsule shaped, biconvex tablets"/>
		Product Color:	<input type="text" value="Lilac"/>
		Product Imprint:	<input 0"="" 1="" line="" on="" other="" score="" side."="" the="" type="text" value="plain on one side and debossed "/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 90 tablets"/>
<input type="checkbox"/> Box/Carton	<input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/>
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Power Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Other: Write In	<input type="text"/> Inner/ Carton/Pack
	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? **Rx billing unit to pharmacy:**
 (Write-in, e.g. 1 Vial)

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
Is product exempt from DSCSA?
GLN:
GCP:
If yes, select exemption:
Other exemption - Write in:
Is product repackaged?
Is product sold by manufacturer's exclusive distributor?
Has FDA granted waiver/exception/exemption for product?
If yes, attach documentation from FDA.
If yes, was original product purchased direct from mfr?
Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.083	2.5	2.5	3	18.75	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	2.35	10	7	4.25	297.5	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722293907"/>	<input type="text" value="00331722293907"/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="10331722293904"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost **Vendor #:**
Invoice Cost (WAC) (\$) **Whsl. Code #:**
As of date: **Fineline Code:**

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION									
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: 1px solid black;"> <tr> <td><input checked="" type="checkbox"/> Organic</td> <td><input type="checkbox"/> Corrosive</td> </tr> <tr> <td><input type="checkbox"/> Inorganic</td> <td><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td><input type="checkbox"/> Steroid/Androgen</td> <td><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p>	<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive								
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer								
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard								
Hazardous Waste Identification									
EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>									
REMS or REGISTRY RESTRICTIONS									
<p>Is there a REMS on this product? <input type="checkbox"/> No If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No Limited Distribution Requirement Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/> NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>									
RETURN INSTRUCTIONS									
<p>Contact tel. # if product received damaged: <input type="text"/> 1-866-827-3647</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/> contact - customerservice@camberpharma.com</p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>									
ADD'L STORAGE INFORMATION									
<p>Is the Product...</p> <table style="width:100%;"> <tr> <td>Controlled Substance? <input type="checkbox"/> No</td> <td>Controlled Substance Code <input type="text"/></td> </tr> <tr> <td>Controlled by State(s)? <input type="checkbox"/> No</td> <td>Listed Chemical (List I or II) <input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable? <input type="checkbox"/> No</td> <td>If yes, indicate which: <input type="text"/></td> </tr> <tr> <td>Schedule No. <input type="text"/></td> <td>Is it a scheduled listed chemical product?: <input type="checkbox"/> No</td> </tr> </table>		Controlled Substance? <input type="checkbox"/> No	Controlled Substance Code <input type="text"/>	Controlled by State(s)? <input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No	ARCOS Reportable? <input type="checkbox"/> No	If yes, indicate which: <input type="text"/>	Schedule No. <input type="text"/>	Is it a scheduled listed chemical product?: <input type="checkbox"/> No
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Controlled by State(s)? <input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No								
ARCOS Reportable? <input type="checkbox"/> No	If yes, indicate which: <input type="text"/>								
Schedule No. <input type="text"/>	Is it a scheduled listed chemical product?: <input type="checkbox"/> No								
CLASS OF TRADE RESTRICTION:									
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>									
MISCELLANEOUS NOTES and/or Image of Product Barcode:									
Release DATE									

