



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): 203083
Medical Device Class, if applicable: _____
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Lansoprazole Delayed-Release Capsules, USP 15 mg
Selling Unit NDC: 31722-570-90 **Unit of Use NDC:** 31722-570-90 **UPC:** 331722570909
UDI _____ **CVX Code:** _____ **MVX Code:** _____
Description: Lansoprazole Delayed-Release Capsules, USP 15 mg
Active Ingredient(s): Lansoprazole, USP
URL for Additional Product Information: www.camberpharma.com
Address: 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: Proton pump inhibitor (PPI)

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?
e. Shelf life:
 Protect product (unit of sale) from light?
 Initial shelf life at launch (if different): _____

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value=""/>
a product kit?	<input type="text" value="No"/>	Is the Product... Unit of Use	<input type="text" value=""/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value=""/>	Orphan Drug Status	<input type="text" value=""/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value=""/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Corn, Alcohol, Sugar"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
correctional institution block?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
opioid?	<input type="text" value="No"/>	Size:	<input type="text" value="90 ct"/>
Cannabinoid?	<input type="text" value="No"/>	Strength:	<input type="text" value="15 mg"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>	Dosage Form:	<input type="text" value="Hard gelatin capsule"/>
If Unit Dose, indicate NDC here:	<input type="text" value=""/>	Product Shape:	<input type="text" value="Capsule"/>
		Product Color:	<input type="text" value="Pink cap and green body"/>
		Product Imprint:	<input type="text" value="Imprinted with 'H' on cap and '166' on body"/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 90 Capsules"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	

Minimum order quantity?
 If Yes, how many of which package type?
 Each
 Inner/ Carton/ Pack
 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?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 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. _____
 GLN:
 GCP:
 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		
Box/Carton/Bundle/ Inner Pack:	0.09	1.5	1.5	3	6.75	1
Case:	2.85	9.5	6.5	4	247	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" value="00331722570909"/>	<input type="text" value="00331722570909"/>
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>		<input type="text" value="30331722570900"/>	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

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

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.



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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>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #003366; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">SDS Hazard Classification</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; padding: 2px;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; padding: 2px;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Inorganic</td> <td style="padding: 2px;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Steroid/Androgen</td> <td style="padding: 2px;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Does the product have an Aerosol class? 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ADD'L STORAGE INFORMATION																																																					
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #003366; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">RETURN INSTRUCTIONS</th> </tr> </thead> <tbody> <tr> <td style="width: 60%; padding: 2px;">Contact tel. # if product received damaged: <input type="text"/></td> <td style="padding: 2px;">1-866-827-3647</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Is product returnable for credit: <input type="checkbox"/> Yes</td> </tr> <tr> <td colspan="2" style="padding: 2px;">URL/Link to returns policy: <input type="text"/></td> </tr> <tr> <td colspan="2" style="padding: 2px;">contact - customerservice@camberpharma.com</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</td> </tr> <tr> <td colspan="2" style="padding: 2px;">If so, which states? Other requirements? Comments? <input type="text"/></td> </tr> </tbody> </table>	RETURN INSTRUCTIONS		Contact tel. # if product received damaged: <input type="text"/>	1-866-827-3647	Is product returnable for credit: <input type="checkbox"/> Yes		URL/Link to returns policy: <input type="text"/>		contact - customerservice@camberpharma.com		Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No		If so, which states? Other requirements? Comments? <input type="text"/>																																							
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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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	Return Instructions
<input type="text"/>	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>