



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

Version 2021 Introduction Type: New Item Final Version Date: 2/25/2026

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212414
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (if Applicable) and Established Name:	Lenalidomide Capsules 20 mg
Selling Unit NDC:	31722-261-21
Unit of Use NDC:	31722-261-21
UPC:	331722261210
UDI	
CVX Code:	
MVX Code:	
Description:	Lenalidomide Capsules 20 mg
Active Ingredient(s):	Lenalidomide
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Immunomodulatory thalidomide analogue antineoplastic agent

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	Excursions permitted to 15° to 30°C (59° – 86°F)
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
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?	<input type="checkbox"/> No <input checked="" type="checkbox"/> *Yes
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="checkbox"/> 24 Months <input type="checkbox"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Direct And Drop-Ship	Size:
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	Is the Product... Orphan Drug Status	Unit of Use
co-licensed?	<input type="checkbox"/> No	FDA Approval Status	Strength:
latex-free?	<input type="checkbox"/> No	Allergens Present	Hard gelatin capsule
preservative-free?	<input type="checkbox"/> Yes	Dairy, Lactose	Product Shape:
correctional institution block?	<input type="checkbox"/> No	Country of Origin	Capsule
opioid?	<input type="checkbox"/> No	India	Product Color:
Cannabinoid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	Brown opaque cap and white opaque body
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		Imprinted with 'H' on cap and 'L6' on body
If Unit Dose, indicate NDC here:			Product Imprint:

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 21 Capsules
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/> Tube	<input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	1 Each
<input type="checkbox"/> Vial Powder Multi	Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Revlimid
	<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
If yes, attach documentation from FDA.	
GLN:	0331722498975
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
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:	0.11	1.60	1.60	2.90	7.42	1
Box/Carton/Bundle/ Inner Pack:						
Case:	2.90	9.84	6.50	4.13	264.15	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	1		00331722261210	00331722261210
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722261214	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$15,118.04	Whsl. Code #:	
As of date:	5/12/2023	Fineline Code:	



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic? Yes
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? Yes
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) Yes
- 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
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is this product regulated for shipment by IATA? (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? No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger No
- Cargo
- Passenger & Cargo

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
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes
- Controlled by State(s)? No Yes
- ARCOS Reportable? No Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No Yes
- If yes, indicate which:
- Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments) No
- Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: Yes
Group 1 items (antineoplastic)

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? Yes No
If Yes, is it managed with a pharmacy registry? Yes No
Website URL:

Med Guide Required Yes No
Limited Distribution Requirement Yes No
Comments / Details: (For example, iPledge program?)

REMS: Yes No
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: Yes No
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: No Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes No
If so, which states? Other requirements? Comments?

Dispensed Product Returns: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to Lenalidomide REMS program. (All States)

Non-Dispensed Product Returns: Return directly to Camber's third party return goods processor. (All States)

Damaged in Transit Returns (bv carrier): Return to Camber Distribution Center. (All States)

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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"/> Yes b. Autofax <input type="checkbox"/> No Fax Number: <input type="text"/> None c. Fax <input type="checkbox"/> No Fax Number: <input type="text"/> None d. Phone only <input type="checkbox"/> No Phone No.: <input type="text"/> None e. Supplier Web Site only <input type="checkbox"/> No Site Address: <input type="text"/> None Minimum Order Quantity: <input type="text"/> 1 Bottle <input type="text"/> Units Supplier's Customer Service Number: <input type="text"/> 866-827-3647 Contracted 3PL company / contact #: Name: <input type="text"/> None Phone: <input type="text"/> None	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> 2:00 PM Monday - Thursday <input type="text"/> Eastern Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> 1 Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> Yes Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> Yes PO Receipt cut off time: <input type="text"/> 12:00 PM <input type="text"/> Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text"/> 12:00 PM Saturday Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text"/> 12:00 PM Order receipt method: Phone: <input type="checkbox"/> No Phone #: <input type="text"/> None Fax: <input type="checkbox"/> No Fax #: <input type="text"/> None EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> No Other fees apply: <input type="checkbox"/> No
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/> Distribution drop-ship to validated Lenalidomide REMS Certified Dispensing Locations only.	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> None Physician Name: <input type="text"/> None Physician/Clinic Phone #: <input type="text"/> None Physician State License #: <input type="text"/> None Physician/Clinic DEA #: <input type="text"/> None Physician/Clinic Specialty: <input type="text"/> None	Contact # if product is received damaged: <input type="text"/> 866-827-3647 Is product returnable for credit: <input type="checkbox"/> No URL/Link to returns policy: https://www.camberpharma.com/partner-resources/#returned-goods-policy Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes If so, which states? Other requirements? Comments? Dispensed Product Returns: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to Lenalidomide REMS program. (All States) Non-Dispensed Product Returns: Return directly to Camber's third party return goods processor. (All States) Damaged in Transit Returns (by carrier): Return to Camber Distribution Center. (All States)
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Yes Is product order for restocking purposes? <input type="checkbox"/> Yes