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

Version 2021 | **Introduction Type:** New Item | x Final Version | **Date:** 6/26/2024

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
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:	Imide immunomodulatory thalidomide analogue (cereblon modulator)

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	No
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product…	Direct And Drop-Ship
Is the Product…	Unit of Use
Orphan Drug Status	
FDA Approval Status	
Allergens Present	Dairy and Lactose
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	21 ct
Strength:	20 mg
Dosage Form:	Hard gelatin capsule
Product Shape:	Capsule
Product Color:	Brown opaque cap and white opaque body
Product Imprint:	Imprinted with 'H' on cap and 'L6' on body

FOR GENERIC DRUG PRODUCTS

Authorized Generic — *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Revlimid

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	Yes
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	
GLN:	0331722498975
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00331722261210	00331722261210
	Box/Carton/Bundle/Inner Pack				
x	Case	24		20331722261214	
	Pallet				

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°C to 30°C (59° – 86° F)
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	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?	No	
Special returns requirements for this product?	*Yes	
d. Store product (unit of sale) upright?	No	
Protect product (unit of sale) from light?	No	
e. Shelf life:	24	**Months**
Initial shelf life at launch (if different):		**Months**

ORDER INFORMATION

Unit of Sale

x	Bottle
	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sgl
	Vial Powder Multi
	Other: Write In

What is the NDC selling unit? 1 Bottle of 21 Capsules (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

1	Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
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:						

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$15,118.04
As of date:	5/12/2023

WHOLESALER USE ONLY:

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.

***Please provide any additional information on page 2.** **See new p. 3 for Designated Drop Ship Only.** **Signature:**

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?	Yes
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
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)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	No

- [ ] Passenger
- [ ] 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#

SDS Hazard Classification

- [x] Organic
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	No
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	Yes
If yes, indicate which:	Group 2 items (non-antineoplastic that meets a hazard criterion)

Hazardous Waste Identification

EPA Hazardous Waste Code:	WT02, MN01, R006	Waste Characteristics	D004

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?	Yes		
If Yes, is it managed with a pharmacy registry?	Yes		
Website URL:	www.lenalidomiderems.com		
Med Guide Required	Yes		
Limited Distribution Requirement	Yes		
Comments / Details: (For example, iPledge program?)	Must be a certified Lenalidomide REMS Program Location		
REMS:	Yes		
REMS Program Manager Name:	Bristol Myers Squibb	Phone:	1-888-423-5436
Supplier Manages REMS registry exclusively:	No		
Wholesale distributor support:	No		
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
		NPI #:	
Comments			
Registry:	Yes		
Registry Program Contact Name:	REMS Call Center	Phone:	1-888-423-5436
Comments	Lenalidomide REMS is a shared REMS program		

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No	Controlled Substance Code	
Controlled by State(s)?	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

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:	

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:	1-888-423-5436
Is product returnable for credit:	No
URL/Link to returns policy:	contact - www.lenalidomiderems.com
Special regulations or returns requirements for this product in certain states?	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 and/or Image of Product Barcode:

Release DATE

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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

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	Yes	Fax Number:	732-562-8788
c. Fax	Yes	Fax Number:	732-562-8788
d. Phone only	No	Phone No.:	None
e. Supplier Web Site only	No	Site Address:	None

Minimum Order Quantity: 1 Bottle — Units

Supplier's Customer Service Number: 732-529-0430 x466 or x467

Contracted 3PL company / contact #: Name: None; Phone: None

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time: 11:00 AM Monday - Thursday — Eastern

Shipping lead time of PO: Hours — 1 Days

Ships same day for next day receipt: Yes

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: No

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: No

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available: No

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: — Phone #: ; Fax: — Fax #: ; EDI:

Overnight Fees apply:

Other fees apply:

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: Distribution drop-ship to validated Lenalidomide REMS Certified Dispensing Locations only.

Other Data Information Required to Process PO:

Patient Procedure Date:	None
Physician Name:	None
Physician/Clinic Phone #	None
Physician State License #	None
Physician/Clinic DEA #:	None
Physician/Clinic Specialty:	None

Miscellaneous Notes:

Return Instructions

Contact # if product is received damaged: 732-529-0430 x466 or x467

Is product returnable for credit: 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? 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)

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? Yes

Is product order for restocking purposes? Yes