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

Version 2021 | **Introduction Type:** New Item | x Final Version | **Date:** 5/17/2023

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:	82-677-4775		
Proprietary Name (If Applicable) and Established Name:	Lenalidomide Capsules 5mg		
Selling Unit NDC:	31722-258-28	**Unit of Use NDC:** 31722-258-28	**UPC:** 331722258289
UDI		**CVX Code:**	**MVX Code:**
Description:	Lenalidomide Capsules 5mg		
Active Ingredient(s):	Lenalidomide		
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:	Immunomodulatory Agent		

ADDITIONAL PRODUCT INFORMATION

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

PRODUCT DESCRIPTION INFORMATION

Size:	28ct
Strength:	5mg
Dosage Form:	hard gelatin capsule
Product Shape:	capsule shaped, size '2'
Product Color:	white opaque cap/white opaque body
Product Imprint:	H' on cap and 'L2' 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	**GLN:**	0331722000000
Is product exempt from DSCSA?	No		
If yes, select exemption:		**GCP:**	
Other exemption - Write in:			
Is product repackaged?	No	**If yes, was original product purchased direct from mfr?**	
Is product sold by manufacturer's exclusive distributor?	Yes		
Has FDA granted waiver/exception/exemption for product?	No	**Provide source manufacturer for repackaged product**	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00331722258289	00331722258289
	Box/Carton/Bundle/Inner Pack				
x	Case	24		20331722258283	
	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		**What is the NDC selling unit?**	
1	Bottle	1 bottle of 28 capsules	
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	**Minimum order quantity?**	Yes
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	**If Yes, how many of which package type?**	
	Vial Powder Sql	1	Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In		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:	0.1	1.5	1.5	2.4	5.6	1
Box/Carton/Bundle/ Inner Pack:						
Case:	2.6	9.8	6.5	4.1	264.2	24
Pallet:						

COST INFORMATION

Regular Cost

Invoice Cost (WAC) ($) $20,157.36

As of date: 4/20/2023

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:

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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?	No
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?	No
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?	No
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?	Yes

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		Corrosive
	Inorganic		Oxidizer
	Steroid/Androgen		Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	Yes
If yes, indicate which:	Group 1 items (antineoplastic)

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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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: Yes

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