



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

Version 2021

Introduction Type: New Item

Final Version

Date: 5/17/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="212414"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text" value="Excursions permitted to 15°C to 30°C (59° – 86° F)"/>			
DUNS: <input type="text" value="82-677-4775"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Lenalidomide Capsules 10mg"/>				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: <input type="text" value="31722-259-28"/>		Unit of Use NDC: <input type="text" value="31722-259-28"/>		UPC: <input type="text" value="331722259286"/>		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
UDI: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: <input type="text" value="Lenalidomide Capsules 10mg"/>				b. Contact for temperature excursion questions:			
Active Ingredient(s): <input type="text" value="Lenalidomide"/>				Name: <input type="text" value="Soma Raju"/>			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				Number: <input type="text" value="732-529-0423"/>			
Address: <input type="text" value="1031 Centennial Ave (and) 800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>			
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>		c. Special regulations for product in any states?			
Phone Number: <input type="text" value="1-866-827-3647"/>		Fax: <input type="text" value="732-562-8788"/>		Special returns requirements for this product? <input type="checkbox"/> No			
Product Therapeutic Classification: <input type="text" value="Immunomodulatory Agent"/>				*Yes <input type="checkbox"/>			
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION				
The product is a legend device? <input type="checkbox"/> No			Is the Product... Direct And Drop-Ship <input type="checkbox"/>				
if yes, enter class # <input type="text"/>			Is the Product... Unit of Use <input type="checkbox"/>				
a product kit? <input type="checkbox"/> No			Orphan Drug Status <input type="checkbox"/>				
if yes, list NDCs of component parts reverse numbered? <input type="text"/>			FDA Approval Status <input type="text"/>				
co-licensed? <input type="checkbox"/> No			Allergens Present <input type="text" value="Dairy and Lactose"/>				
latex-free? <input type="checkbox"/> Yes			Country of Origin <input type="text" value="India"/>				
preservative-free? <input type="checkbox"/> Yes			Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No				
correctional institution block? <input type="checkbox"/> No			Size: <input type="text" value="28ct"/>				
opioid? <input type="checkbox"/> No			Strength: <input type="text" value="10mg"/>				
Cannabinoid? <input type="checkbox"/> No			Dosage Form: <input type="text" value="hard gelatin capsule"/>				
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			Product Shape: <input type="text" value="capsule shaped, size '0'"/>				
If Unit Dose, indicate NDC here: <input type="text"/>			Product Color: <input type="text" value="orange opaque cap/white opaque body"/>				
			Product Imprint: <input type="text" value="H' on cap and 'L4' on body"/>				
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: <input type="text" value="Revlimid"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="0331722000000"/>					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>		Provide source manufacturer for repackaged product <input type="text"/>			
Other exemption - Write in: <input type="text"/>							
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. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC			
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>		<input type="text"/>			
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		<input type="text"/>		<input type="text"/>			
<input checked="" type="checkbox"/> Case		<input type="text" value="24"/>		<input type="text"/>			
<input type="checkbox"/> Pallet		<input type="text"/>		<input type="text"/>			
				GTIN-14			
				<input type="text" value="00331722259286"/>			
				Unit of Use GTIN-14			
				<input type="text" value="00331722259286"/>			
COST INFORMATION			WHOLESALE USE ONLY:				
Regular Cost <input type="text"/>			Vendor #: <input type="text"/>				
Invoice Cost (WAC) (\$) <input type="text" value="\$20,157.36"/>			Whsl. Code #: <input type="text"/>				
As of date: <input type="text" value="4/20/2023"/>			Fineline Code: <input type="text"/>				
ORDER INFORMATION							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> 1 Bottle		<input type="text" value="1 bottle of 28 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"/> Yes					
<input type="checkbox"/> Tube							
<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		<input type="text" value="1"/> Each					
<input type="checkbox"/> Vial Power Multi		Inner/ Carton/ Pack					
<input type="checkbox"/> Other: Write In <input type="text"/>		Case					
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text"/>		Rx billing unit to pharmacy:					
(Write-in, e.g. 1 Vial)		<input type="checkbox"/> Each					
		<input type="checkbox"/> Gram					
		<input type="checkbox"/> Milliliter					
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.08	1.6	1.6	2.9	7.42	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	2.82	9.84	6.5	4.13	264.15	24	
Pallet:							

*Please provide any additional information on page 2.

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

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)

- 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
- 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#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No
- Controlled by State(s)? No
- ARCOS Reportable? No
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No
- If yes, indicate which:
- 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:

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: 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

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 (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"/> Yes Fax Number: 732-562-8788 c. Fax <input type="checkbox"/> Yes Fax Number: 732-562-8788 d. Phone only <input type="checkbox"/> No Phone No.: None e. Supplier Web Site only <input type="checkbox"/> 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	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: <input type="checkbox"/> Yes Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> No
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:	Overnight receipt available: <input type="checkbox"/> No PO Receipt cut off time: 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: 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 <input type="checkbox"/> Yes Restricted to retail pharmacy only: <input type="checkbox"/> No Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: Distribution drop-ship to validated Lenalidomide REMS Certified Dispensing Locations only.	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: None Physician Name: None Physician/Clinic Phone #: None Physician State License #: None Physician/Clinic DEA #: None Physician/Clinic Specialty: None	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? <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
	Is product order for scheduled patient procedure? <input type="checkbox"/> Yes Is product order for restocking purposes? <input type="checkbox"/> Yes