

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	5/17/	/2023
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperatu	ire - Indicate the USP temp	erature range for t	nis product.			
Application Number for NDA/AN	NDA/BLA (drug); PN	/IA/510(k)(med devi	ce):	21	2414		<u> </u>		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica								1	· -					
DUNS:	82-677-4775								Other Temperature Range	Requirement	Excursions p	ermitted to 1	5°C to 30°C (	(59° – 86° F)
Proprietary Name (If Applicable) a	and Established Na	me: Lenali	idomide Capsules 20mg					I	(write in)					
Selling Unit NDC:	31722-261-21		Unit of Use NDC:		31722-261-21		1722261210		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Lenalidomide Cap	sules 20mg						Ţ	Is this product to be shippe	d to customers on i	ce?		No	1
									Is this product to be shippe				No	
Active Ingredient(s):		Lenalidomide												
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharma			_				Name:		Soma Raju			
Address:		Ave (and) 800 Center	nnial Ave, Suite 1		State:	Address 2:			Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@ca	ip: 08854		Group E-mail:		somaraju@h	ieterousa.coi	<u>n</u>	
Phone Number:	1-866-827-3647	,			Fax:	732-562-8788	imberphanna.com	c Special re	gulations for product in any	etatos?			No	1
Product Therapeutic Classificatio		Immunomodulatory	/ Agent			102 002 0100		o. opeciai ie	Special returns requiremen				*Yes	-
Troduct merapeano orassineano	JII.	illinianoinoudiator)	7 / 190111						opeciai retarris requiremen	is for this product:			103	1
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT DES	CRIPTION INFORMATION	I d Store proc	luct (unit of sale) upright?				No	1
The weedwat is 2				Direct And D	ron-Shin			ui otoro proc		ala) fuama limba?				1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	nop-Snip		21ct	e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	Offit of Ose		Size:	2101	e. Shelf life:	Initial shelf life at launch (	if different):			24	Months
a product kit?		No	Orphan Drug Status				20mg		illiuai sileli ille at laulicii (	ii dillerelli).				Wionins
if yes, list NDCs of		110	FDA Approval Status			Strength:	259			ORDER INFORM	IATION			
component parts						Danama Farmi	hard gelatin capsule							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						1 Bottle		1 bottle of 21	capsules		
latex-free?		Yes	Dairy ar	nd Lactose		Product Shape:	capsule shaped, size '0'		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	,						Ampule					
correctional institution block?		No				Product Color:	brown opaque cap/white		Glass		Minimum or	der quantity	1?	Yes
opioid?		No	0	to de-			opaque body		Tube					
Cannabinoid?  If Unit Dose, is item bar coded to u	it dans for	No	Country of Origin	India		Product Imprint:	H' on cap and 'L6' on body		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of wh	ich package t	tuno?
hospital scanning?	unit dose for		Is this product covered to	inder the			body		Vial Powder Sql			Each	ісп раскаўе і	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No				Vial Power Multi			Inner/Cartor	/Pack	
				,					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS				-						
					Aut	thorized Generic *If	Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			T		se	ction fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Revlimid										Each	,-	
								(Write-in, e.g	. 1 Vial)	-		Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA defini		er?	Yes No	_	GLN:	0331722000000			ITEN	AND PACKING II	NFORMATION	N		
Is product exempt from DSCSA?			INO .											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msn	•	Volume	Saleable #
Other exemption - Write in:									g 2201	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		10	No Yes	_		iginal product purcha	sed	Item/Each:	0.08	1.6	1.6	2.9	7.424	1 1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No	-	direct from m	rr ? se manufacturer for re		Box/Carton/E	Down all a /					
If yes, attach documentation fro		ouuci :	140		Frovide Source	e manuracturer for re	packageu product	Inner Pack:	oundle/					
ii yes, attacii accanentation no	mi DA.							Case:						
		GT	IN AND HIBCC PRODUCT I	NFORMATION				1	2.9	9.84	6.5	4.13	264.1548	24
								Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14							
X Item/Each		1			0033	31722261210	00331722261210							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			2033	31722261214		11						
Pallet								Regular Cost		04= 110 - :	Vendor #:	и.		
	_							Invoice Cost	(VVAC) (\$)	\$15,118.04	Whsl. Code			
								As of date:	4/20/2023		Fineline Co	uc.		
								713 of date.	0, _0_					
											1			
											1			
			Attach copy of SAFETY D	ATA SHEET (SI	DS) or non hazai	rd letter, PACKAGE INS	SERT, LABEL AND PHOTO OF I	PRODUCT PACK	AGING and BARCODE.					



## **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?  No	SDS Hazard Classification
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:
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	Is the product a NIOSH hazardous drug? If yes, indicate which:  Group 1 items (antineoplastic)
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: WT02, MN01, R006 Waste Characteristics D004
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:  Yes  Yes  www.lenalidomiderems.com
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)  Yes Yes Must be a certified Lenalidomide REMS Program Location
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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  Pyes Bristol Myers Squibb No  No  DEA #: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments
SP#	Registry:  Registry Program Contact Name:  REMS Call Center  Phone: 1-888-423-5436
ADD'L STORAGE INFORMATION	Comments Lenalidomide REMS is a shared REMS program
Is the Product  Controlled Substance?  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  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:	Contact tel. # if product received damaged:  Is product returnable for credit:  No
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  contact - www.lenalidomiderems.com
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?
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)
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:



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#### Version 2021

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Desig	nated Drop Ship Product	Standard Order Receipt and Processing
Contracted 3PL company / contact #: Name: Phone:	Fax Number: 732-562-8788 Fax Number: 732-562-8788	Purchase order daily receipt cut off time by supplier Cut off time:  11:00 AM Monday - Thursday
Expedited freight fees billed with each order:	Yes	Overnight receipt available: No
Drop Ship service fee billed with each order:	No	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	No	Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday  Priority Overnight receipt available:
Class of Tra	de Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices o Restricted from US territories? (explain in comments	hospitals, clinics and physician offices  No  No  No	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information	Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscelland	eous Notes:	Contact # if product is received damaged:  Is product returnable for credit:  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?  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?  Is product order for restocking purposes?  Yes  Yes