



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

Version 2021 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name:  Application:   
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):   
 Medical Device Class, if applicable:   
 DUNS:   
 Proprietary Name (If Applicable) and Established Name:   
 Selling Unit NDC:  Unit of Use NDC:  UPC:   
 UDI:  CVX Code:  MVX Code:   
 Description:   
 Active Ingredient(s):   
 URL for Additional Product Information:   
 Address:  Address 2:   
 City:  State:  Zip:   
 Key Contact:  Email:   
 Phone Number:  Fax:   
 Product Therapeutic Classification:

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Notes:   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?   
**b. Contact for temperature excursion questions:**  
 Name:   
 Number:   
 Group E-mail:   
**c. Special regulations for product in any states?**  
 Special returns requirements for this product?    
**d. Store product (unit of sale) upright?**   
**e. Shelf life:** Protect product (unit of sale) from light?   
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="text" value="No"/>	Is the Product... Direct And Drop-Ship	<input type="text"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Unit of Use	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text"/>
latex-free?	<input type="text" value="Yes"/>	FDA Approval Status	<input type="text"/>
preservative-free?	<input type="text" value="Yes"/>	Allergens Present	<input type="text" value="Dairy and Lactose"/>
correctional institution block?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="India"/>
opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
Cannabinoid?	<input type="text" value="No"/>	Size:	<input type="text" value="21ct"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Strength:	<input type="text" value="25mg"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Dosage Form:	<input type="text" value="hard gelatin capsule"/>
		Product Shape:	<input type="text" value="capsule shaped, size '0'"/>
		Product Color:	<input type="text" value="white opaque cap/white opaque body"/>
		Product Imprint:	<input type="text" value="H' on cap and 'L7' on body"/>

**ORDER INFORMATION**

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

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Rx billing unit to pharmacy:  
 (Write-in, e.g. 1 Vial)  Each  
 Gram  
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?   
 Is product exempt from DSCSA?   
 If yes, select exemption:  
 Other exemption - Write in:   
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exception/exemption for product?   
 If yes, attach documentation from FDA.   
 GLN:   
 GCP:   
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.11	1.60	1.60	2.90	7.42	1
Case:	2.99	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	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722262217"/>	<input type="text" value="00331722262217"/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="20331722262211"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Fineline Code:



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

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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:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/>	NFPA Storage Level: <input type="text"/>
Is the product a NIOSH hazardous drug? <input type="checkbox"/> Yes	Group 1 items (antineoplastic) <input type="text"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code: <input type="text" value="WT02, MN01, R006"/>	Waste Characteristics <input type="text" value="D004"/>

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

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text" value="1-888-423-5436"/>	Is product returnable for credit: <input type="checkbox"/> No
URL/Link to returns policy: <input type="text" value="contact - www.lenalidomiderems.com"/>	
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes	If so, which states? Other requirements? Comments? <input type="text"/>

**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)



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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	Standard Order Receipt and Processing										
Purchase orders may be accepted by: <table border="1"> <tr><td>a. EDI</td><td><input type="checkbox"/> Yes</td></tr> <tr><td>b. Autofax</td><td><input type="checkbox"/> Yes</td></tr> <tr><td>c. Fax</td><td><input type="checkbox"/> Yes</td></tr> <tr><td>d. Phone only</td><td><input type="checkbox"/> No</td></tr> <tr><td>e. Supplier Web Site only</td><td><input type="checkbox"/> No</td></tr> </table> Fax Number: 732-562-8788 Fax Number: 732-562-8788 Phone No.: None 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	a. EDI	<input type="checkbox"/> Yes	b. Autofax	<input type="checkbox"/> Yes	c. Fax	<input type="checkbox"/> Yes	d. Phone only	<input type="checkbox"/> No	e. Supplier Web Site only	<input type="checkbox"/> No	<b>Purchase order daily receipt cut off time by supplier</b> 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
a. EDI	<input type="checkbox"/> Yes										
b. Autofax	<input type="checkbox"/> Yes										
c. Fax	<input type="checkbox"/> Yes										
d. Phone only	<input type="checkbox"/> No										
e. Supplier Web Site only	<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:	<b>Overnight receipt available:</b> <input type="checkbox"/> No PO Receipt cut off time: Days of week overnight is available: <table border="1"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <b>Priority Overnight receipt available:</b> PO Receipt Cut off time: <b>Saturday Overnight receipt available:</b> PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<input type="checkbox"/>	Monday										
<input type="checkbox"/>	Tuesday										
<input type="checkbox"/>	Wednesday										
<input type="checkbox"/>	Thursday										
<input type="checkbox"/>	Friday										
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: <a href="https://www.camberpharma.com/partner-resources/#returned-goods-policy">https://www.camberpharma.com/partner-resources/#returned-goods-policy</a> 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										