



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

Version 2024 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION**

Company Name:  Application:   
 Application Number for NDA/ANDA/BLA; PMA/510(k):  NDA 505(b) Type:   
 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:

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

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?   
 Protect product (unit of sale) from light?

e. Shelf life:  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Is the Product... Orphan Drug Status	Direct And Drop-Ship Unit of Use <input type="text"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Gluten, Oats, Wheat, Spelt, Barley"/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
correctional institution block? opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	<input type="text" value="21 ct"/>
		Strength:	<input type="text" value="2 mg"/>
		Dosage Form:	<input type="text" value="Hard gelatin capsule"/>
		Product Shape:	<input type="text" value="Capsule"/>
		Product Color:	<input type="text" value="Opaque white cap and&lt;br/&gt;opaque brown body"/>
		Product Imprint:	<input type="text" value="Imprinted with 'H' on cap&lt;br/&gt;and 'P2' on body"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> 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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<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?   
 (Write-in, e.g. 1 Vial)  
 HCPCS J-Code:

Rx billing unit to pharmacy:  
 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:	0.06	1.50	1.50	2.48	5.58	1
Case:	1.2	7.0	5.5	4.38	168.63	12
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722771214	00331722771214
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	12		20331722771218	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					

**COST INFORMATION**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:

**WHOLESALE USE ONLY:**  
 Vendor #:   
 Whsl. Code #:   
 Fineline Code:



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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?  Yes
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
  - 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  No
- 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#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes
- Controlled by State(s)?  No  Yes
- ARCOS Reportable?  No  Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II)  No  Yes
- If yes, indicate which:
- Is it a scheduled listed chemical product?:  No  Yes

### 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:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  Yes  No  
If Yes, is it managed with a pharmacy registry?  Yes  No  
Website URL:

Med Guide Required  Yes  No  
Limited Distribution Requirement  Yes  No  
Comments / Details: (For example, iPledge program?)

REMS:  Yes  No  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  Yes  
Wholesale distributor support:  No  Yes  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

Registry:  Yes  No  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  No  Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  Yes  No  
If so, which states? Other requirements? Comments?

Dispensed Product Returns: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to PS-Pomalidomide 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		Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> No Fax Number: <input type="text"/> None c. Fax <input type="checkbox"/> No Fax Number: <input type="text"/> None d. Phone only <input type="checkbox"/> No Phone No.: <input type="text"/> None e. Supplier Web Site only <input type="checkbox"/> No Site Address: <input type="text"/> None Minimum Order Quantity: <input type="text"/> 1 Bottle <input type="text"/> Units Supplier's Customer Service Number: <input type="text"/> 866-827-3647 Contracted 3PL company / contact #: Name: <input type="text"/> None Phone: <input type="text"/> None		<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> 2:00 PM Monday - Thursday <input type="text"/> Eastern Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> 1 <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes	
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: <input type="text"/>		<b>Overnight receipt available:</b> <input type="checkbox"/> No PO Receipt cut off time: <input type="text"/> 12:00 PM <input type="text"/> Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text"/> 12:00 PM <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text"/> 12:00 PM Order receipt method: Phone: <input type="checkbox"/> No <input type="checkbox"/> Phone #: Fax: <input type="checkbox"/> No <input type="text"/> Fax #: EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> No Other fees apply: <input type="checkbox"/> No	
Class of Trade Restriction:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/> Distribution drop-ship to validated PS-Pomalidomide REMS Certified Dispensing Locations only.			
Other Data Information Required to Process PO:		Return Instructions	
Patient Procedure Date: <input type="text"/> None Physician Name: <input type="text"/> None Physician/Clinic Phone #: <input type="text"/> None Physician State License #: <input type="text"/> None Physician/Clinic DEA #: <input type="text"/> None Physician/Clinic Specialty: <input type="text"/> None		Contact # if product is received damaged: <input type="text"/> 866-827-3647 Is product returnable for credit: <input type="checkbox"/> 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?	
Miscellaneous Notes:		Dispensed Product Returns: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to PS-Pomalidomide 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? <input type="checkbox"/> Yes Is product order for restocking purposes? <input type="checkbox"/> Yes	