



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 6/23/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="202438"/>				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"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Famciclovir Tablets 500 mg"/>		Unit of Use NDC: <input type="text" value="31722-708-30"/>		UPC: <input type="text" value="331722708302"/>			
Selling Unit NDC: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: <input type="text" value="Famciclovir Tablets 500 mg"/>				Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Active Ingredient(s): <input type="text" value="Famciclovir, USP"/>				Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				<b>b. Contact for temperature excursion questions:</b>			
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Name: <input type="text" value="Soma Raju"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>		Number: <input type="text" value="732-529-0423"/>	
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
Phone Number: <input type="text" value="1-866-827-3647"/>		Fax: <input type="text" value="732-562-8788"/>		<b>c. Special regulations for product in any states?</b>			
Product Therapeutic Classification: <input type="text" value="Nucleoside analog DNA polymerase inhibitor"/>				Special returns requirements for this product? <input type="text" value="No"/>			
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>			
The product is a legend device? <input type="text" value="No"/>		Is the Product... Direct-Ship Only <input type="text"/>		Size: <input type="text" value="30 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... Unit of Use <input type="text"/>		Strength: <input type="text" value="500 mg"/>			
a product kit? <input type="text" value="No"/>		Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="Film coated tablet"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Oval, biconvex"/>			
co-licensed? <input type="text" value="No"/>		Allergens Present <input type="text" value="Lactose"/>		Product Color: <input type="text" value="Off white"/>			
latex-free? <input type="text" value="Yes"/>		Country of Origin <input type="text" value="India"/>		Product Imprint: <input type="text" value="Debossed with 'I' on one side and '48' on the other side"/>			
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? <input type="text" value="No"/>							
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"/>							
<b>FOR GENERIC DRUG PRODUCTS</b>							
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="Famvir"/>							
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0331722498975"/>					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="text" value="No"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>				<input type="text" value="00331722708302"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack						<input type="text" value="20331722708306"/>	
<input checked="" type="checkbox"/> Case		<input type="text" value="48"/>				Unit of Use GTIN-14 <input type="text" value="00331722708302"/>	
<input type="checkbox"/> Pallet							
<b>ORDER INFORMATION</b>							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle		<input type="text" value="1 Bottle of 30 Tablets"/>					
<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="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 Powder Multi		<input type="text" value="48"/> Each					
<input type="checkbox"/> Other: Write In		<input type="text" value="Inner/ Carton/ Pack"/>					
		<input type="text" value="Case"/>					
<b>PHARMACY ORDER / BILL UNIT</b>							
Rec. sell unit to customer? <input type="text"/>		Rx billing unit to pharmacy:					
(Write-in, e.g. 1 Vial)		<input type="text" value="Each"/>					
		<input type="text" value="Gram"/>					
		<input type="text" value="Milliliter"/>					
<b>ITEM AND PACKING INFORMATION</b>							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
	Depth	Width	Height				
Item/Each:	0.09	1.5	1.5	3	6.75	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	4.85	12.5	9.5	4.5	534.38	48	
Pallet:							
<b>COST INFORMATION</b>				<b>WHOLESALE USE ONLY:</b>			
Regular Cost <input type="text"/>		Vendor #: <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="\$34.95"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text" value="7/7/2017"/>		Fineline Code: <input type="text"/>					

\*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?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- 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 Substance Code
- Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes      If yes, indicate which:
- Schedule No.       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  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  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:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

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

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

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

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647  
Is product returnable for credit:  No  Yes

URL/Link to returns policy:  contact - customerservice@camberpharma.com

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

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

