



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"/>		a. Temperature – Indicate the USP temperature range for this product.		Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="203834"/>				Other Temperature Range Requirement (write in): <input type="text" value="Store between 15° and 25° C."/>		Notes: <input type="text"/>	
Medical Device Class, if applicable: <input type="text"/>				Is this product to be shipped to customers on ice? <input type="checkbox"/> No		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
DUNS: <input type="text" value="11-856-3719"/>		Acyclovir Tablets, USP 800 mg		b. Contact for temperature excursion questions:		Name: <input type="text" value="Soma Raju"/>	
Propriet Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/>		Acyclovir Tablets, USP 800 mg		Number: <input type="text" value="732-529-0423"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>	
Selling Unit NDC: <input type="text" value="31722-778-05"/>		Unit of Use NDC: <input type="text"/>		UFC: <input type="text" value="331722778053"/>			
UDI: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: <input type="text" value="Acyclovir Tablets, USP 800 mg"/>				c. Special regulations for product in any states?		Special returns requirements for this product? <input type="checkbox"/> No	
Active Ingredient(s): <input type="text" value="Acyclovir, USP"/>				d. Store product (unit of sale) upright?		<input type="checkbox"/> No	
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				e. Shelf life:		Protect product (unit of sale) from light? <input type="checkbox"/> No	
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Initial shelf life at launch (if different): <input type="text"/>		Months: <input type="text"/>	
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>		Months: <input type="text"/>	
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
Phone Number: <input type="text" value="1-866-827-3647"/>		Fax: <input type="text" value="732-562-8788"/>					
Product Therapeutic Classification: <input type="text" value="Synthetic nucleoside analogue antiviral"/>							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="checkbox"/> No		Is the Product... <input type="checkbox"/> Direct-Ship Only		Size: <input type="text" value="500 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... <input type="checkbox"/> Neither		Strength: <input type="text" value="800 mg"/>			
a product kit? <input type="checkbox"/> No		Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="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="checkbox"/> No		Allergens Present <input type="text"/>		Product Color: <input type="text" value="Blue"/>			
latex-free? <input type="checkbox"/> Yes		Country of Origin <input type="text" value="India"/>		Product Imprint: <input type="text" value="Debossed with 'J' on one side and '50' on the other side"/>			
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							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
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="Zovirax"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="0331722498975"/>					
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		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>				<input type="text" value="00331722778053"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input checked="" type="checkbox"/> Case		<input type="text" value="6"/>				<input type="text" value="20331722778057"/>	
<input type="checkbox"/> Pallet							
						Unit of Use GTIN-14 <input type="text"/>	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="\$105.88"/>		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text" value="4/15/2024"/>				Fineline Code: <input type="text"/>			
ORDER INFORMATION							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle		<input type="text" value="1 Bottle of 500 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="checkbox"/> Yes					
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl		If Yes, how many of which package type?					
<input type="checkbox"/> Vial Liquid Multi		<input type="text" value="6"/> Each					
<input type="checkbox"/> Vial Powder Sgl		<input type="text"/>					
<input type="checkbox"/> Vial Powder Multi		<input type="text"/>					
<input type="checkbox"/> Other: Write In		<input type="text"/>					
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 Saleable #	
				Depth Width Height		(Cube) Pieces	
Item/Each:		<input type="text" value="1.4"/>		<input type="text" value="3.75 3.75 8"/>		<input type="text" value="112.5 1"/>	
Box/ Carton/ Bundle/ Inner Pack:							
Case:		<input type="text" value="9"/>		<input type="text" value="12 8 9"/>		<input type="text" value="864 6"/>	
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: <input type="text"/>			



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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) No

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) No

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: No

Passenger
 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#

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
 NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

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

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

REMS: No

REMS Program Manager Name: Phone:
 Supplier Manages REMS registry exclusively:
 Wholesale distributor support:
 Provider Name: DEA #:
 Site Enrollment Number assigned by Supplier: NCPDP#:
 NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:
 Comments

ADD'L STORAGE INFORMATION

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

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes

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

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

