



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 7/12/2021

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="201506"/>				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="022490515"/>				Notes <input type="text"/>			
Proprietary Name (if Applicable) and Established Name: <input type="text" value="Valacyclovir HCl Capsules"/>		Unit of Use NDC: <input type="text" value="3-59746-324-30-8"/>		Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: <input type="text" value="59746-324-30"/>		CVX Code: <input type="text"/>		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI <input type="text"/>		MVX Code: <input type="text"/>					
Description: <input type="text" value="Valacyclovir Hydrochloride 500mg 30ct Capsules"/>				b. Contact for temperature excursion questions:			
Active Ingredient(s): <input type="text" value="Valacyclovir HCl"/>				Name: <input type="text" value="Customer Service"/>			
URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/>				Number: <input type="text" value="(800) 313-4623"/>			
Address: <input type="text" value="207 Kiley Drive"/>		Address 2: <input type="text"/>		Group E-mail: <input type="text" value="customer.service@cadista.com"/>			
City: <input type="text" value="Salisbury"/>		State: <input type="text" value="MD"/>					
Key Contact: <input type="text" value="Jackie Emershaw"/>		Zip: <input type="text" value="21801"/>					
Phone Number: <input type="text" value="(410) 912-3722"/>		Email: <input type="text" value="Jackie.Emershaw@jubl.com"/>					
Product Therapeutic Classification: <input type="text" value="Antiviral"/>		Fax: <input type="text" value="(215) - 443 - 9646"/>					
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION				
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size: <input type="text" value="30 count"/>					
if yes, enter class # <input type="text"/>	Is the Product... Neither <input type="checkbox"/>	Strength: <input type="text" value="500mg"/>					
a product kit? <input type="checkbox"/> No	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="CAPSULE"/>					
if yes, list NDCs of component parts <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Capsule"/>					
reverse numbered? <input type="checkbox"/> No	Allergens Present <input type="text"/>	Product Color: <input type="text" value="Blue"/>					
co-licensed? <input type="checkbox"/> No	Country of Origin <input type="text" value="IN"/>	Product Imprint: <input type="text" value="C324 500"/>					
latex-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No						
preservative-free? <input type="checkbox"/> No							
correctional institution block? <input type="checkbox"/> Yes							
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="Valtrex"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="8902805000006"/>					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text" value="0359746"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
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	Unit of Use GTIN-14			
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00359746324308"/>	<input type="text"/>			
<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="48"/>	<input type="text"/>	<input type="text" value="40359746324306"/>	<input type="text"/>			
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
ORDER INFORMATION			PHARMACY ORDER / BILL UNIT				
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle	<input type="text"/>	<input type="text" value="1 bottles of 30 capsule"/>					
<input type="checkbox"/> Box/Carton	<input type="text"/>	(Write-in, e.g. 1 Box of 10 Vials)					
<input type="checkbox"/> Ampule	<input type="text"/>	Minimum order quantity? <input type="checkbox"/> Yes					
<input type="checkbox"/> Glass	<input type="text"/>						
<input type="checkbox"/> Tube	<input type="text"/>						
<input type="checkbox"/> Vial Liquid Sgl	<input type="text"/>	If Yes, how many of which package type?					
<input type="checkbox"/> Vial Liquid Multi	<input type="text"/>	<input type="text" value="48"/> Each					
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>	<input type="text"/>					
<input type="checkbox"/> Vial Power Multi	<input type="text"/>	<input type="text"/>					
<input type="checkbox"/> Other: Write In	<input type="text"/>	<input type="text"/>					
<input type="text"/>	<input type="text"/>	<input type="text"/>					
<input type="text"/>	<input type="text"/>	<input type="text"/>					
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)		Volume (Cube)	Saleable # Pieces		
		Depth	Width	Height			
Item/Each:	0.13	1.87	1.87	4.37	15.28		
Box/Carton/Bundle/Inner Pack:					0.00		
Case:	7.35	15.25	11.75	5.5	985.53		
Pallet:					48		
				0.00			
COST INFORMATION			WHOLESALE USE ONLY:				
Regular Cost	<input type="text"/>	Vendor #:		<input type="text"/>			
Invoice Cost (WAC) (\$)	<input type="text" value="\$17.22"/>	Whsl. Code #:		<input type="text"/>			
As of date:	<input type="text"/>	Fineline Code:		<input type="text"/>			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

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)  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#

### 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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify  No

NFPA Storage Level:

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  No

Comments / Details: (For example, iPledge program?)

#### REMS:

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:

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

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



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>