



# 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"/>		<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="22314"/>				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="Clonidine HCl ER Tablets"/>		Unit of Use NDC: <input type="text"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="59746-668-60"/>		UPC: <input type="text" value="3-59746-668-60-0"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
UDI <input type="text"/>		CVX Code: <input type="text"/>					
MVX Code: <input type="text"/>							
Description: <input type="text" value="Clonidine Hydrochloride Extended Release 0.1mg 60ct Tablet"/>				<b>b. Contact for temperature excursion questions:</b>			
Active Ingredient(s): <input type="text" value="Clonidine Hydrochloride"/>				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="Attention Deficit Hyperactivity Disorder (ADHD)"/>		Fax: <input type="text" value="(215) - 443 - 9646"/>					
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION				
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="60 count"/>					
if yes, enter class # <input type="text"/>	Is the Product... Neither <input type="text"/>	Strength: <input type="text" value="0.1mg"/>					
if yes, list NDCs of product kit? <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="TABLETS"/>					
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Round"/>					
co-licensed? <input type="text" value="No"/>	Allergens Present <input type="text"/>	Product Color: <input type="text" value="White"/>					
latex-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="IN"/>	Product Imprint: <input type="text" value="C / N4"/>					
preservative-free? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>						
correctional institution block? <input type="text" value="Yes"/>							
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"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB1"/>		<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable					
II. Generic Equivalent to What Brand?: <input type="text" value="Kapvay"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="8902805000006"/>					
Is product exempt from DSCSA? <input type="text" value="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="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="No"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="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="00359746668600"/>	<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="40359746668608"/>	<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"/>			
<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 bottle of 60 tablets"/>					
<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="text" value="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"/>	<input type="text" value="Each"/>				
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>	<input type="text"/>	<input type="text" value="Inner/Carton/Pack"/>				
<input type="checkbox"/> Vial Power Multi	<input type="text"/>	<input type="text"/>	<input type="text" value="Case"/>				
<input type="checkbox"/> Other: Write In	<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:	0.37	1.9	1.9	4	14.44	1	
Box/Carton/Bundle/Inner Pack:					0.00		
Case:	4.85	12.5	9.45	4.41	520.93	48	
Pallet:					0.00		
COST INFORMATION			WHOLESALE USE ONLY:				
Regular Cost	<input type="text"/>	Vendor #:		<input type="text"/>			
Invoice Cost (WAC) (\$)	<input type="text" value="\$20.00"/>	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?  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?  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      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:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

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

Release DATE

### 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?



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