



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

Version 2021

Introduction Type: New Product 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="075317"/>				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="Terazosin HCl Capsules"/>		Unit of Use NDC: <input type="text" value="3-59746-384-10-4"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="59746-384-10"/>		UPC: <input type="text"/>		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="Terazosin Hydrochloride 2mg 1000ct Capsules"/>				b. Contact for temperature excursion questions:			
Active Ingredient(s): <input type="text" value="Terazosin 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="Benign Prostatic Hypertrophy"/>		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="1000 count"/>					
if yes, enter class # <input type="text"/>	Is the Product... Neither <input type="text"/>	Strength: <input type="text" value="2mg"/>					
if yes, list NDCs of product kit? <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="CAPSULE"/>					
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Capsule, Size 3"/>					
co-licensed? <input type="text" value="No"/>	Allergens Present <input type="text"/>	Product Color: <input type="text" value="Ivory"/>					
latex-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="US"/>	Product Imprint: <input type="text" value="TL 384"/>					
preservative-free? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>						
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							
<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable							
I. Orange Book Rating: <input type="text" value="AB"/>							
II. Generic Equivalent to What Brand?: <input type="text" value="Hytrin"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0359746000004"/>					
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="00359746384104"/>	<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="12"/>	<input type="text"/>	<input type="text" value="40359746384102"/>	<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							
Unit of Sale			What is the NDC selling unit?				
<input checked="" type="checkbox"/> Bottle			<input type="text" value="1 bottle of 1000 capsules"/>				
<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			If Yes, how many of which package type?				
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="12"/>	Each					
<input type="checkbox"/> Vial Power Multi	<input type="text"/>	Inner/Carton/Pack					
<input type="checkbox"/> Other: Write In	<input type="text"/>	Case					
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text" value="1 bottle of 1000 capsules"/>			Rx billing unit to pharmacy:				
(Write-in, e.g. 1 Vial)			<input checked="" type="checkbox"/> Each				
			<input type="checkbox"/> Gram				
			<input type="checkbox"/> Milliliter				
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.66	3.5	3.5	6.3	77.18	1	
Box/Carton/Bundle/Inner Pack:					0.00		
Case:	3.5	14.25	10.75	7.75	1187.20	12	
Pallet:					0.00		
COST INFORMATION			WHOLESALE USE ONLY:				
Regular Cost			Vendor #:	<input type="text"/>			
Invoice Cost (WAC) (\$)		\$176.40	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:

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify <input type="checkbox"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="checkbox"/> No <input style="width: 100%; border: 1px solid black;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input style="width: 100%;" type="text"/> Waste Characteristics: <input style="width: 100%;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: Wholesale distributor support: <input style="width: 100%;" type="text"/></p> <p>Provider Name: <input style="width: 100%;" type="text"/> DEA #: <input style="width: 100%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/> NCPDP#: <input style="width: 100%;" type="text"/></p> <p>NPI #: <input style="width: 100%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <p>Registry Program Contact Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No <input type="checkbox"/> Yes Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No <input type="checkbox"/> Yes Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</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 style="width: 100%;" type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" 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 style="width: 100%;" type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<input style="width: 100%; height: 100%;" type="text"/>							



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

Version 2021

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"/>	Purchase order daily receipt cut off time by supplier 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"/>	Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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:	
<input type="text"/>	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>