



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: Jubilant Cadista Pharmaceuticals Inc.		Application: ANDA		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): 209605				Other Temperature Range Requirement (write in):		<input type="text"/>	
Medical Device Class, if applicable:				Notes:		<input type="text"/>	
DUNS: 022490515		Proprietary Name (If Applicable) and Established Name: Tizanidine HCl Capsules		Is this product to be shipped to customers on ice?		<input type="checkbox"/> No	
Selling Unit NDC: 59746-671-34		Unit of Use NDC:		Is this product to be shipped to customers on dry ice?		<input type="checkbox"/> No	
UDI:		CVX Code:		b. Contact for temperature excursion questions:			
Description: Tizanidine Hydrochloride 4mg 150ct Tablets		UPC: 3-59746-671-34-1		Name: Customer Service			
Active Ingredient(s): Tizanidine Hydrochloride		MVX Code:		Number: (800) 313-4623			
URL for Additional Product Information: www.cadista.com/products/full-product-list		Address 1: 207 Kiley Drive		Group E-mail: customer.service@cadista.com			
Address: 207 Kiley Drive		State: MD		Address 2:			
City: Salisbury		Email: Jackie.Emershaw@jubl.com		Zip: 21801			
Key Contact: Jackie Emershaw		Fax: (215) - 443 - 9646		c. Special regulations for product in any states?		<input type="checkbox"/> No	
Phone Number: (410) 912-3722				Special returns requirements for this product?		<input type="checkbox"/> No	
Product Therapeutic Classification: Muscle Relaxant				d. Store product (unit of sale) upright?		<input type="checkbox"/> No	
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION			
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/> No	Size: 150 count	Unit of Sale: <input checked="" type="checkbox"/> Bottle	What is the NDC selling unit? <input type="text" value="1 bottle of 150 tablets"/>			
if yes, enter class # a product kit? <input type="checkbox"/> No	Is the Product... Orphan Drug Status <input type="checkbox"/> Neither	Strength: 4mg	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status: <input type="text"/>	Dosage Form: CAPSULE	<input type="checkbox"/> Ampule	Minimum order quantity? <input type="checkbox"/> Yes			
co-licensed? <input type="checkbox"/> No	Allergens Present: <input type="text"/>	Product Shape: Capsule, Size 3	<input type="checkbox"/> Glass	If Yes, how many of which package type?			
latex-free? <input type="checkbox"/> Yes	Country of Origin: IN	Product Color: Light Blue	<input type="checkbox"/> Tube	<input type="text" value="48"/> Each			
preservative-free? <input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No	Product Imprint: C / 671	<input type="checkbox"/> Vial Liquid Sgl	<input type="text"/>			
correctional institution block? <input type="checkbox"/> Yes			<input type="checkbox"/> Vial Liquid Multi	<input type="text"/>			
opioid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>			
Cannabinoid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Power Multi	<input type="text"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			<input type="checkbox"/> Other: Write In	<input type="text"/>			
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Zanaflex							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 8902805000006					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746					
If yes, select exemption: Other exemption - Write in: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>		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: <input checked="" type="checkbox"/> Item/Each	Saleable Quantity: 1	HIBCC:	GTIN-14: 00359746671341	Unit of Use GTIN-14: <input type="text"/>			
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input checked="" type="checkbox"/> Case	48		40359746671349				
<input type="checkbox"/> Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		Invoice Cost (WAC) (\$): \$39.99		Vendor #:		<input type="text"/>	
As of date: <input type="text"/>				Whsl. Code #:		<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 <input type="checkbox"/> Yes</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 <input type="checkbox"/> No</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
<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>Purchase order daily receipt cut off time by supplier</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>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <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>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>