

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

						Introduction Typ	e: Post Launch Chan	nge		Final Version			Date:	6/9/2	2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista Pharm	aceuticals Inc.				Applicatio	n: ANDA		a. Temperature – Indica	ate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANDA			):	043	862					ture Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable			,							0					
DUNS:	022490515								Other Te	mperature Range F	Requirement				
Proprietary Name (If Applicable) and		Prednis	one Tablets						(wr	ite in)					
•	59746-175-06		Unit of Use NDC:				-59746-175-06-1		Notes						
UDI			CVX Code:			MVX Code:									
Description: F	Prednisone 20mg 100	Tablets							Is this pr	oduct to be shipped	to customers on i	ce?		No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Prednisone															
									b. Contact for temperature excursion questions: Name: Customer Service						
URL for Additional Product Informat Address:	207 Kiley Drive	w.cadista.com	/products/full-product	t-list	1	Address 2:			Name:			(800) 313-46			
	Salisbury				State:		Zip: 21801		Number: Group E			customer.		dista com	
	Customer Service				Email:	customer.service			Croup E	man.		customer.	Scivice@co	uista.com	
	(800) 313-4623				Fax:	N/A			c. Special regulations f	or product in any	states?			No	
Product Therapeutic Classification:	Cor	ticosteroid								eturns requirement				No	
					1										
	ADDITIONA	L PRODUCT INF				PRODUCT DE	SCRIPTION INFORMATION	N	d. Store product (unit o	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly					product (unit of sa	le) from light?			No	
a legend device?	No		Is the Product	Neither	· · ·	Cine.	100 count		e. Shelf life:		·, -····a····			24	Months
if yes, enter class #			Orphan Drug Status			Size:				elf life at launch (i	if different):				Months
a product kit?	No					Strength:	20mg								
if yes, list NDCs of			FDA Approval Status			ou chgui.					ORDER INFORM	IATION			
component parts						Dosage Form:	TABLETS					MR			
reverse numbered?	No								Unit of S	Bottle		What is the 1 bottle of 10		unit?	
co-licensed? latex-free?	No		Allergens Present				Round			Box/Carton			g. 1 Box of 1	0 \/iale)	
preservative-free?	No	·				Product Shape	: Round			Ampule		(winte-iii, e.	g. 1 Dox 01 1	0 viais)	
correctional institution block?	Yes						Peach			Glass		Minimum or	der quantity	?	Yes
opioid?	No					Product Color:				Tube			,		
Cannabinoid?	No		Country of Origin	US		Product Imprin	TL 175			Vial Liquid Sgl					
If Unit Dose, is item bar coded to uni	it dose for					rioduct imprin				Vial Liquid Multi				ch package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	FAA)?	Yes					Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR							Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					A	thorized Generic *	If Authorized Generic, other			РН	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			-			ection fields are not applical		Rec. sell unit to custon			Rx billing u	nit to phorm	2014	
II. Generic Equivalent to What Brand		tasone®							1 bottle of 10		1	X	Each	acy.	
ii. Generie Equivalent to What Brane		autonite							(Write-in, e.g. 1 Vial)			~	Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	MATION								Milliliter		
Does supplier meet DSCSA definition	on of manufacturer?		Yes	_	GLN:	0359746000004				ITEN	I AND PACKING II	NFORMATION	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ons (US msm	-	Volume	Saleable #
Other exemption - Write in:									-	morgin Luo.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product purch	ased		Item/Each:	0.15	1.9	1.9	4	14.44	1
Is product sold by manufacturer's end Has FDA granted waiver/exception/e			No No	_	direct from n	nfr? ce manufacturer for r			Box/Carton/Bundle/						
			INU		Provide sour	ce manufacturer for i	epackaged product		Inner Pack:					0.00	
If yes attach documentation from									Case:						
If yes, attach documentation from	FDA.									7.9	15.5	11.75	5.25	956.16	48
If yes, attach documentation from	FDA.	GTIN	AND HIBCC PRODUCT I	NFORMATION							10.0	11.70			
If yes, attach documentation from	FDA.	GTIN	AND HIBCC PRODUCT I	NFORMATION				;	Pallet:		13.5	11.75		0.00	
Saleable Unit of Measure		GTIN ble Quantity	AND HIBCC PRODUCT I	NFORMATION		N-14	Unit of Use GTIN-14		Pallet:		13.5	11.10		0.00	
Saleable Unit of Measure				NFORMATION		N-14 59746175061	Unit of Use GTIN-14				13.3				
Saleable Unit of Measure X Item/Each Box/Cartor/BundleInner Pack		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14			TINFORMATION	10.0		WHOLESALI	0.00 ER USE ONL	Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case				NFORMATION	003		Unit of Use GTIN-14		COS	TINFORMATION	10.0		WHOLESAL		Y:
Saleable Unit of Measure		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14		COS Regular Cost	TINFORMATION		Vendor #:			Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14		COS	TINFORMATION		Vendor #: WhsI. Code	#:		Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14		COS Regular Cost Invoice Cost (WAC) (\$)	TINFORMATION		Vendor #:	#:		Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14		COS Regular Cost	TINFORMATION		Vendor #: WhsI. Code	#:		Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case		ble Quantity		NFORMATION	003	59746175061	Unit of Use GTIN-14		COS Regular Cost Invoice Cost (WAC) (\$)	TINFORMATION		Vendor #: WhsI. Code	#:		Y:
Saleable Unit of Measure X Iterr/Each Box/Cantor/Bundle/Inner Pack X Case		1 48	HIBCC		403	59746175061	Unit of Use GTIN-14		COS Regular Cost Invoice Cost (WAC) (\$) As of date:			Vendor #: WhsI. Code	#:		Y:

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No     SDS Hazard Classification       No     Organic     Corrosive       No     Inorganic     Oxidizer       No     Steroid/Androgen     Contact Hazard       No     Does the product have an Aerosol class? If yes, identify NFPA Storage Level:     No       No     NFPA Storage Level:     Image: Contact Hazard
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No     Is the product a NIOSH hazardous drug?     No       If yes, indicate which:     If yes, indicate which:         Hazardous Waste Identification         Image: No         EPA Hazardous Waste Code:         Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: 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	No       REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       Is there a REMS on this product?         If Yes, is it managed with a pharmacy registry?       No         Website URL:       No         No       Med Guide Required         Limited Distribution Requirement       No         Comments / Details: (For example, iPledge program?)       No         REMS:       Phone:         Supplier Manages REMS registry exclusively:       Phone:         Wholesale distributor support:       Provider Name:         Site Enrollment Number assigned       DEA #:
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	by Supplier:     NPI #:       Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No     RETURN INSTRUCTIONS       No     Contact tel. # if product received damaged:       Is product returnable for credit:     URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS NOTES and/or Image of Product Barcode:



## **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         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:         Hours       Days         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available:       Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is 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:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?