

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

Version 2021						Introduction 1	ype:	Post Launch Change			l Version			Date:	1/12/	/2021
			PRODUCT INFORMA	TION						SF	PECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista F	Pharmaceuticals Inc.				Applicati	ion:	ANDA	a. Temperatur	re - Indicate th	e USP temper	ature range for th	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203253								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:																
DUNS:	022490515									Other Tempera	ature Range R	equirement				
Proprietary Name (If Applicable)	and Established Na	ame: Spiron	olactone Tablets						1	(write in)		•				
Selling Unit NDC:	59746-218-01		Unit of Use NDC:			UPC:	3-59746	6-218-01-0		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Spiropolactone 1	00mg 100 Tablets							i	la thia product	to be objected	to customers on id	202		No	1
Description.	Spironolacione 1	oomg too rablets										to customers on d			No	-
Active Ingredient(s):		Spironolactone								is this product	to be shipped	to customers on a	ily ice:		INO	1
Active ingredient(s).		Ophonolacione							b. Contact for	temperature e	excursion que	stions:				
URL for Additional Product Inforr	nation:	www.cadista.co	m/products/full-produc	t-list					Di Comaction	Name:	wouldion quo		Customer S	ervice		
Address:	207 Kiley Drive	- Triviodaistaico	ny productoy ran produc	<u> </u>		Address 2:				Number:			(800) 313-4			
City:	Salisbury				State:	MD	Zip:	21801		Group E-mail	:			service@ca	dista.com	
Key Contact:	Jackie Emershaw	,			Email:	Jackie.Emersha										
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646			c. Special reg	ulations for pr	oduct in any s	states?			No	1
Product Therapeutic Classification	n:	Antihypertensive										for this product?			No	1
·										•						1
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT D	ESCRIP	PTION INFORMATION	d. Store produ	uct (unit of sale	e) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv				11	Protect produ		a) from light?			No	i
a legend device?		No	Is the Product	Neither	9		1	100 count	e. Shelf life:	Frotect produ	ici (uniii or sai	e) iroin light?			24	Months
if yes, enter class #		INO	Orphan Drug Status	TTOTALICI		Size:		100 Count	e. onen me.	Initial shelf lif	o at launch (if	different):			24	Months
a product kit?		No	Orphian Drug Status				1	100mg		illidai sileli ili	e at launch (ii	umerenty.				Months
if yes, list NDCs of		INU	FDA Approval Status			Strength:		roomg				ORDER INFORM	ATION			
component parts			. Dr. rippi o vai otatao				7	TABLET								
reverse numbered?		No				Dosage Form	n:   i			Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							X Bottl	e		1 bottles of			
latex-free?		Yes	7 mor gono i rocom				F	Round, Biconvex			Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shap	pe:	,		Amp			, , , ,	5	,	
correctional institution block?		Yes					E	Brown		Glas	s		Minimum o	rder quantity	?	Yes
opioid?		No				Product Colo	or:			Tube	9					
Cannabinoid?		No	Country of Origin	IN		Book doors book	1	TL 218		Vial	Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Product Impr	int:				Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the			_			Vial	Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (*	ΓAA)?	No					Vial	Power Multi			Inner/Carton	/Pack	
										Othe	er: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS									ĺ			
					Au	thorized Generic		orized Generic, other			PHA	RMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section	fields are not applicable	Rec. sell unit	to customer?			Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	ınd?:	Aldactone							1 bo	ttles of 100 tabl	lets		Х	Each	-	
									(Write-in, e.g.	1 Vial)				Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFORI	MATION									Milliliter		
		_		_												
Does supplier meet DSCSA defin	ition of manufactu	rer /	Yes No	-	GLN:	8902805000006					IIEM	AND PACKING IN	NEORMATIO	<b>V</b>		
Is product exempt from DSCSA?			INU						!							
If yes, select exemption:					GCP:	0359746				w	eight Lbs.		ons (US msr	-	Volume	Saleable #
Other exemption - Write in:			Na								J	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product			Item/Each:		0.19	1.9	1.9	4	14.44	1
Is product sold by manufacturer's			No No			irect from mfr?			- 10 . 15							
Has FDA granted waiver/exception		roduct?	INU		Provide sour	ce manufacturer for	r repack	kaged product	Box/Carton/B	undle/					0.00	
If yes, attach documentation fro	m FDA.			l					Case:							
		GTII	N AND HIBCC PRODUCT I	NEORMATION					l Case.		11.56	15.63	11.89	6.1	1133.63	48
									Pallet:							
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14							0.00	
X Item/Each		1			003	59746218010	1									
Box/Carton/Bundle/Inner Pack							1			COST INF	ORMATION			WHOLESALI	ER USE ONL	Y:
X Case		48			403	59746218018										
Pallet							1		Regular Cost				Vendor #:			
									Invoice Cost (	(WAC) (\$)		\$38.86				
													Fineline Co	de:		
									As of date:							
1													<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SDS	S) or non haza			, LABEL AND PHOTO OF F	PRODUCT PACKA		RCODE.					
*Please provide any additional in								ated 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 SDS Hazard Classification b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? (if yes, answer a-e below and provide SDS) If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion) a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo REMS: Is this a reportable quantity? RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS 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: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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

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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 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:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday						
Class of Trade Restriction:  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:  Other Data Information Required to Process PO:	Priority Overnight receipt available:  PO Receipt Cut off time:  Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply:  Other fees apply:  Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?						
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?						