

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

Version 2021						Introduction Typ	e: Post Launch Change		x Final Version			Date:	7/12/	/2021
			PRODUCT INFORMA	TION					SPECIAL HAN	OLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista F	Pharmaceuticals Inc.				Application	: ANDA	a. Temperature -	- Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 200221									Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicable:														
DUNS:	022490515							0	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable)		ame: Olanza	apine ODT						(write in)					
Selling Unit NDC:	59746-307-32		Unit of Use NDC:			UPC: 3-	59746-307-32-5	- N	otes					
UDI			CVX Code:			MVX Code:								
	01	Natara maria a Tablara									_			1
Description:	Olanzapine Oral L	Disintegrating Tablets	Turng 30ct						this product to be shipped				No	-
Andrew Income Provides		Olanzapine						_ IS	this product to be shipped	to customers on o	ary ice?		No	
Active Ingredient(s):		Olarizapine						h Contact for to	mperature excursion que	otiona				
URL for Additional Product Inforr	nation:	www.cadista.com	m/products/full-produc	t lict				-	ame:	sations.	Customer S	envice		
Address:	207 Kiley Drive	www.cauista.coi	II/products/ruii-produc	t-list		Address 2:			umber:		(800) 313-4			
City:	Salisbury				State:		ip: 21801		roup E-mail:			service@ca	dista com	
Key Contact:	Jackie Emershaw	,					@jubl.com		oup = main		<u>castomer.</u>	SCI VICCIO CC	raista.com	
Phone Number:	(410) 912-3722					(215) - 443 - 9646	<u>C juonooni</u>	c. Special regula	tions for product in any	states?			No	1
Product Therapeutic Classification		Antipsychotic				(',			pecial returns requirement				No	
Trouble morapound diagonious								-	ooda rotamo roquiromoni	o for time product.				
	ADDITI	ONAL PRODUCT INI	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	1
The was dead in 0				Direct-Ship On	hz			-1		I-) f !!!-10				1
The product is?			Is the Product	Unit Dose	ily		00		otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit Dose		Size:	30 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status				10	In	itial shelf life at launch (f different):				Months
a product kit?		No	FD4 4			Strength:	10mg			ORDER INFORM	AATION			
if yes, list NDCs of component parts			FDA Approval Status				TABLET, ODT			OKDEK INFORK	IATION			
reverse numbered?		No				Dosage Form:	TABLET, ODT	11	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 carton of 3		unit:	
latex-free?		Yes	Allergens Fresent				Round		X Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape	rtourid		Ampule		(vviite iii, e	g. 1 Dox 01 1	o viais)	
correctional institution block?		Yes					Yellow		Glass		Minimum o	rder quantity	12	Yes
opioid?		No				Product Color:	1 0.1011		Tube			uo. quantity	•	
Cannabinoid?		No	Country of Origin	IN			D10 / CO		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	,g			Product Imprin	:		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?	unii 4000 101	Yes	Is this product covered u	inder the					Vial Powder Sql		48	Each	pg-	.,,,,,
If Unit Dose, indicate NDC here:		59746-307-12	Trade Agreements Act (No				Vial Power Multi		- 10	Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS								1		
					Au	thorized Generic *I	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			_			ction fields are not applicable	Rec. sell unit to	customer?		Ry hilling u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Zyprexa Zydis						_	on of 30 tablets	1	X	Each	acy.	
Express Eyes						(Write-in, e.g. 1 Vial)			Gram					
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFORM	IATION			(Willo III, Olg. 1	na.,			Milliliter		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter														
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:	8902805000006			ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:	0359746				Dimensi	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:						-		_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	l li	f yes, was or	iginal product		Item/Each:	0.04	1.0	1.0	4	44.44	1
Is product sold by manufacturer's	s exclusive distrib	utor?	No	F	ourchased di	rect from mfr?			0.01	1.9	1.9	4	14.44	
Has FDA granted waiver/exception	n/exemption for p	roduct?	No	F	Provide sour	ce manufacturer for r	epackaged product	Box/Carton/Bun	dle/				0.00	
If yes, attach documentation fro	m FDA.							Inner Pack:					0.00	
								Case:	5.75	13.78	12.99	5.91	1057.90	48
		GTII	N AND HIBCC PRODUCT IN	NFORMATION					****					
	_							Pallet:					0.00	
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each		1			003	59746307325			COST INFORMATION		_	WHOLESALI	ED LIGE ON	V
Box/Carton/Bundle/Inner Pack		40			400	E0746207222			COST INFORMATION			WHOLESAL	ER USE UNL	- I ·
X Case		48			403	59746307323		Regular Cost			Vendor #:			
Pallet								Invoice Cost (WA	(C) (\$)	607.74		#-		
	-							invoice Cost (WA	(a)	\$37.71	Fineline Co			
	-							As of date:			I menne Co	uc.		
								As or date.						
	_													
			Attach conv of SAFETY DA	TA SHEET (SDS)	or non hazai	rd letter PACKAGE IN	SERT, LABEL AND PHOTO OF	PRODUCT PACKAGE	NG and BARCODE		1			
*Please provide any additional in		•		311221 (303)	, c. nom nazar		signated Drop Ship Only.		gnature:					



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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? No (if yes, answer a-e below and provide SDS) If yes, indicate which: 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 Is this a reportable quantity? REMS: 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



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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?						