

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

Version 2021						Introduction Ty	vpe: Post Launch Change		x Final Version			Date:	7/12	/2021
			PRODUCT INFORMA	TION			-		SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc.					Applicati	on: ANDA	a. Temperature – Indicate the USP temperature range for			this product.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212218							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:														
DUNS:	022490515								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame:	Clomipramine HCI Capsules						(write in)					
Selling Unit NDC:	59746-710-30		Unit of Use NDC				3-59746-710-30-9		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Clomipramine Hy	drochloride 25n	ng 30ct Capsules						Is this product to be shippe				No	]
									Is this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s): Clomipramine Hydrochloride b. Contact for temperature excursion questions:														
URL for Additional Product Inform	nation:	www.cadis	ta.com/products/full-products	rt-list				b. contact it	Name:	estions.	Customer S	ervice		
Address:	207 Kiley Drive					Address 2:			Number:		(800) 313-4	623		
City:	Salisbury	y State:				MD	Zip: 21801		Group E-mail: <u>customer.service@cadista.con</u>				adista.com	
Key Contact:	Jackie Emershaw	1			Email:	Jackie.Emersha	w@jubl.com							1
Phone Number:	(410) 912-3722	1			Fax:	(215) - 443 - 9646		c. Special re	gulations for product in any				No	
Product Therapeutic Classificatio	n:	Antidepressa	nt						Special returns requiremen	ts for this product?			No	
			CT INFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d Store prov	duct (unit of colo) unright?				No	1
The second second second	ADDITI	ONAL PRODU		Direct Ching	Only	- TRODUCT D	LOOKII HON INFORMATION	u. Store proc	duct (unit of sale) upright?					1
The product is? a legend device?		No	Is the Product Is the Product	Direct-Ship Neither	Unity		30 count	e. Shelf life:	Protect product (unit of sa	aie) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	Interarter		Size:	30 COUNT	e. Shen me.	Initial shelf life at launch (	if different).			24	Months
a product kit?		No	orphan Drug otatus				25mg			in amerency.				montais
if yes, list NDCs of			FDA Approval Status			Strength:	, , , , , , , , , , , , , , , , , , ,			ORDER INFORM	IATION			
component parts						Dosage Form	CAPSULES							
reverse numbered?		No				Desagerenn			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 3			
latex-free? preservative-free?		Yes No				Product Shap	e: Capsule, Size 2		Box/Carton Ampule		(vvrite-in, e	.g. 1 Box of 1	u viais)	
correctional institution block?		Yes					White / Yellow	-	Glass		Minimum o	rder quantity	1?	Yes
opioid?		No				Product Colo			Tube			· · · · · · · · · · · · · · · · · · ·		
Cannabinoid?		No	Country of Origin	US		Product Impri	C / 710		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					i roduct impli			Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered						Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act	TAA)	Yes				Vial Power Multi Other: Write In			Inner/Cartor Case	1/Pack	
			FOR GENERIC DRUG PR	ODUCTS		· · · · · · · · · · · · · · · · · · ·			Other. write in		_	Case		
			TON GENERIC DROG TR	000013										
					Au	uthorized Generic	*If Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB				·		section fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Anafranil						1 b	ottle of 30 capsules		X	Each	•	
							(Write-in, e.g. 1 Vial) Gram							
		DRUG S	UPPLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0359746000004			ITEN	I 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			riginal product		Item/Each:	0.07	1.8	1.8	3	9.72	1
Is product sold by manufacturer's		-	No	_	-	irect from mfr?							0.72	
Has FDA granted waiver/exceptio If yes, attach documentation from		roduct?	No		Provide sour	ce manufacturer for	repackaged product	Box/Carton/I	Bundle/				0.00	
If yes, attach documentation from	m FDA.							Case:						
			GTIN AND HIBCC PRODUCT I	NFORMATION				ouso.	2.16	11	7.5	4.25	350.63	24
								Pallet:					0.00	
Saleable Unit of Measure	S	Saleable Quanti	ty HIBCC		GTI	N-14	Unit of Use GTIN-14						0.00	
X Item/Each	1 00359746710309							COST INFORMATION			WHOLESALER USE ONLY:			
Box/Carton/Bundle/Inner Pack		24			403	59746710307			COST INFORMATION			WHOLESAL	ER USE UNL	
Pallet		24			403			Regular Cos	t		Vendor #:			
								Invoice Cost		\$145.74	Whsl. Code	#:		
											Fineline Co			
								As of date:						
μ				T. 0							1			
		•	Attach copy of SAFETY D	ATA SHEET (SE	US) or non haza		NSERT, LABEL AND PHOTO C	IF PRODUCT PACK						
*Please provide any additional inf	ormation on page	z.				See new p. 3 for l	Designated Drop Ship Only.		Signature:					

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

Version 2021 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 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? No Does the product label bear a CA Prop 65 warning? No c. Contact Hazard? No d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No (If yes, answer a-e below and provide SDS) a. UN/Identification Number	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify       No         NFPA Storage Level:       No         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       No							
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA? No (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 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 Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Pervision (listed in Column 7 of 49 CFR 172.101); SP#	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No       REMS:     Phone:       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:							
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS							
Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If yes, indicate which:       If yes, indicate which:         Schedule No.       Is it a scheduled listed chemical product?:       No         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:	Contact tel. # if product 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?							
MISCELLA	NEOUS 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:	Overnight receipt available:         PO Receipt cut off time:         Days of week overnight is available:         Monday         Tuesday         Wednesday         Thursday         Friday
Class of Trade Restriction:	Priority Overnight receipt available: 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)	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? Is product order for restocking purposes?