

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

Version 2021						Introduction 1	Type: Post Launch	h Change		x Final Version			Date:	6/12/	/2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*	*	
Company Name:	Jubilant Cadista	Pharmaceuticals Inc.				Applica	tion: ANE	DA	a. Temperature – I	ndicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN			e):	212	218					perature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical										,					
DUNS:	022490515								Oth	er Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established N	lame: Clomip	ramine HCI Capsules						[	(write in)					
Selling Unit NDC:	59746-710-30		Unit of Use NDC:			UPC:	3-59746-710-30-9		Note	es					
UDI			CVX Code:			MVX Code:									
Description:	Clomipramine H0	CI 25mg 30ct Capsules	3						Is th	is product to be shippe	d to customers on i	ice?		No	1
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Clomipramine Hydrochloride b. Contact for temperature excursion questions:															
URL for Additional Product Inform	ation.	www.cadista.com	n/products/full-product	t-lict					b. Contact for tem Nan		estions:	Customer S	anvico		
Address:	207 Kiley Drive	www.cadista.com		<u>c noc</u>		Address 2:				nber:		(800) 313-46			
City:	Salisbury				State:	MD	Zip: 21801			up E-mail:		customer.		dista.com	
Key Contact:	Customer Servic	e			Email:	customer.serv	ice@cadista.com			•					
Phone Number:	(800) 313-4623				Fax:	N/A			c. Special regulati	ons for product in any	states?			No	]
Product Therapeutic Classificatio															
	ADDIT	IONAL PRODUCT INF	FORMATION			PRODUCT	DESCRIPTION INFORM	IATION	d. Store product (u	init of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly					tect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	30 count		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initi	al shelf life at launch (	if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	25mg				ORDER INFOR				
component parts			PDA Approval Status				Capsule				ORDER IN ORI	MATION			
reverse numbered?		No				Dosage Forr	n:		Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							X Bottle		1 Bottles of			
latex-free?		Yes				Product Sha	Capsule, Size 2	2		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No				riouuci sha	-			Ampule					
correctional institution block?		Yes				Product Cole	White / Yellow			Glass		Minimum o	rder quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?	unit daga far	No	Country of Origin	US		Product Imp	rint: C 710'			Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ch package t	h/mo?
If Unit Dose, is item bar coded to u hospital scanning?	unit dose for		Is this product covered u	inder the						Vial Powder Sql			Each	ch package t	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes					Vial Power Multi		24	Inner/Carton	/Pack	
				,						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS									4		
					Au	thorized Generic	*If Authorized Generic,				IARMACY ORDER				
I. Orange Book Rating:	AB						section fields are not a	pplicable	Rec. sell unit to cu		-	Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Brand?: Anafranil®					1 Bottles of 30 Capsules				x Each Gram						
			Y CHAIN SECURITY ACT (		MATION				(Write-in, e.g. 1 Via	11)			Gram Milliliter		
		DRUG SUPPL	- GHAIN OLCONIT FACT (	Joodan INFOR									, winniter		
Does supplier meet DSCSA defini	ition of manufactu	urer?	Yes		GLN:	0359746000004				ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Woint I he	Dimens	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product pur	chased		Item/Each:	0.07	1.8	1.8	3	9.72	1
Is product sold by manufacturer's			No		direct from m								-		
Has FDA granted waiver/exceptio If yes, attach documentation from		broduct?	No		Provide sour	ce manufacturer fo	r repackaged product		Box/Carton/Bundle Inner Pack:	e/				0.00	
in yes, attach documentation not	ini DA.								Case:						
		GTI	N AND HIBCC PRODUCT I	NFORMATION						2.16	11	7.5	4.25	350.63	24
									Pallet:					0.00	
Saleable Unit of Measure	:	Saleable Quantity	HIBCC			N-14	Unit of Use G	TIN-14						0.00	
X Item/Each		1 00359746710309													
Box/Carton/Bundle/Inner Pack		24			40359746710307					WHOLESALER USE ONLY:					
X Case Pallet		24			403	03740710307	-		Regular Cost			Vendor #:			
							-		Invoice Cost (WAC	:) (\$)	\$145.74	Whsl. Code	#:		
	-									·/ (*/	\$140.74	Fineline Co			
									As of date:						
μ												1			
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza										
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:															

## **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?