

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

Version 2021						Introduction T	ype: Pos	t Launch Change		x	Final Version			Date:	6/9/2	2023
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*	*	
Company Name: Jubilant Cadista Pharmaceuticals Inc. ANDA Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN			ce):	212	2218		-		airemperata		ture Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat											0					
DUNS:	022490515									Other Ter	nperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Clomi	pramine HCI Capsules						Ι	(wri	te in)					
Selling Unit NDC:	59746-711-90		Unit of Use NDC:				3-59746-711-9	0-0		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Clomipramine HC	CI 50mg 90ct Capsule	s							Is this pro	duct to be shipped	d to customers on i	ce?		No	1
Is this product to be shipped to customers on dry ice? No									]							
Active Ingredient(s): Clomipramine Hydrochloride																
URL for Additional Product Information: www.cadista.com/products/full-product-list							b. Contact for temperature excursion questions: Name: Customer Service									
Address:	207 Kiley Drive	www.cadista.co	m/products/full-produc	<u>t-list</u>	1	Address 2:				Name: Number:			(800) 313-46			
City:	Salisbury				State:	MD	Zip: 2180			Group E-	mail·		customer.		dista com	
Key Contact:	Customer Service	8			Email:	customer.servi				Group L	man.		customer.	Scivice@co	uista.com	
Phone Number:	(800) 313-4623	-			Fax:	N/A	<u>eee caaistan</u>	<u></u>	c. Special reg	ulations f	or product in any	states?			No	1
Product Therapeutic Classification	n:	Antidepressant			1										No	1
Product Therapeutic Classification: Antidepressant Special returns requirements for this product? No																
	ADDITI	IONAL PRODUCT IN	IFORMATION			PRODUCT D	DESCRIPTION	INFORMATION	d. Store prod	uct (unit o	f sale) upright?				No	]
The product is?			Is the Product	Direct-Ship O	nly				]	Protect r	product (unit of sa	le) from liaht?			No	1
a legend device?		No	Is the Product	Neither		Size	90 cou	nt	e. Shelf life:		,	,			24	Months
if yes, enter class #			Orphan Drug Status			Size:				Initial sh	elf life at launch (	if different):				Months
a product kit?	-	No		-		Strength:	50mg									
if yes, list NDCs of			FDA Approval Status			ou chgui.						ORDER INFORM	IATION			
component parts						Dosage Form	n: Capsul	Э					14/1			
reverse numbered?		No	Allermone Dresent							Unit of S	ale Bottle		1 Bottle of 9	NDC selling	unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Conqui	e, Size 1			Box/Carton			g. 1 Box of 1	0 \/iolo\	
preservative-free?		No				Product Shap	pe: Capsul	5, 5126 1			Ampule		(winte-in, e.	g. I Dox of h	5 viais)	
correctional institution block?		Yes					White				Glass		Minimum o	der quantity	?	Yes
opioid?		No				Product Colo	or:				Tube			,		
Cannabinoid?		No	Country of Origin	US		Product Impr	C 711'				Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for					r roudet impr					Vial Liquid Multi				ch package t	type?
hospital scanning?			Is this product covered u								Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	Yes						Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR			1					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS					_							
					Au	uthorized Generic	*If Authorized	Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			_				are not applicable	Rec. sell unit	to custom				nit to pharm	acv:	
I. Generic Equivalent to What Brand?: Anafranil®						1 Bottle of 90 Capsules				x     Each						
							(Write-in, e.g. 1 Vial)				Gram					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																
									_							
Does supplier meet DSCSA definit	tion 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					Weight Lbs.		ons (US msn	-	Volume	Saleable #
Other exemption - Write in:											noight 2001	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product purc	hased		Item/Each:		0.14	2	2	4	16.00	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No No		direct from n	nfr? ce manufacturer for	r ronackagad	roduct	Box/Carton/B	undle/						
If yes, attach documentation from			NO		FIOVICE SOUL	ce manufacturer for	r repackageu j	rouuci	Inner Pack:	unule/					0.00	
									Case:			10.5	0.5	5.05	F 67 04	04
		GT	IN AND HIBCC PRODUCT I	NFORMATION							4.41	12.5	8.5	5.25	557.81	24
									Pallet:						0.00	
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			IN-14	Unit c	f Use GTIN-14							0.00	
X Item/Each	Box/Carton/Bundle/Inner Pack														~	
								COST INFORMATION					WHOLESALI	ER USE ONL	Y:	
X         Case         24         403597           Pallet				59/46/11908	9746711908			Demotes Occi			Vendor #:					
Panet	1				-				Regular Cost Invoice Cost			¢407.40	Vendor #: Whsl. Code	<b>#</b> ·		
	-				-				invoice cost	(1170) (9)		φ437.40	Fineline Co			
							1		As of date:							
							1						1			
	-															
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter, PACKAGE	INSERT, LABE	L AND PHOTO OF P	PRODUCT PACKA	GING and	BARCODE.					
*Please provide any additional info	ormation on page	2.				See new p. 3 for I	Designated Dr	op Ship Only.		Signatur	e:					

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3							
TAM	TERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No SDS Hazard Classification							
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?	Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard							
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     Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No     NFPA Storage Level:       No     No							
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	No     Is the product a NIOSH hazardous drug?     No       If yes, indicate which:							
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification           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	No REMS or REGISTRY RESTRICTIONS							
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?     No       If Yes, is it managed with a pharmacy registry?     Image: Compare the system of							
Is the product restricted for air shipment? If so, indicate restriction:           Passenger           Cargo           Passenger & Cargo	No         Med Guide Required         No           Limited Distribution Requirement         No           Comments / Details: (For example, iPledge program?)         No							
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?	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support:							
No         (if yes, identify method below)           Limited Quantity         Consumer Commodity, ORM-D           Small Quantity (49 CFR 173.4)	Provider Name: Site Enrollment Number assigned by Supplier: DEA #: NCPDP#: NPI #:							
Special Permit; DOT-SP Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments							
ADD'L STORAGE INFORMATION	Registry:     Phone:       Registry Program Contact Name:     Phone:       Comments							
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	RETURN INSTRUCTIONS							
ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?:	No     Contact tel. # if product received damaged:       No     Is product returnable for credit:							
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	VRL/Link to returns policy:							
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states?         4         12.5         8.5         5.25							
Comments:	If so, which states? Other requirements? Comments?							
Mis	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?