



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 6/17/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc.		Application: 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: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: 022490515				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: Clomipramine HCl Capsules				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 59746-712-30		Unit of Use NDC:		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI:		CVX Code:		b. Contact for temperature excursion questions:			
Description: Clomipramine HCl 75mg 30ct Capsules		MVX Code:		Name: Customer Service			
Active Ingredient(s): Clomipramine Hydrochloride				Number: (800) 313-4623			
URL for Additional Product Information: www.cadista.com/products/full-product-list				Group E-mail: customer.service@cadista.com			
Address: 790 Township Line Road		Address 2: Suite 325		c. Special regulations for product in any states?			
City: Yardley		State: PA		Special returns requirements for this product? <input type="checkbox"/> No			
Key Contact: Customer Service		Zip: 19067		d. Store product (unit of sale) upright?			
Phone Number: (800) 313-4623		Email: customer.service@cadista.com		Protect product (unit of sale) from light? <input type="checkbox"/> No			
Product Therapeutic Classification: Antidepressant		Fax: N/A		e. Shelf life:			
				Initial shelf life at launch (if different): <input type="text"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: 30 count			
if yes, enter class # a product kit? <input type="checkbox"/> No		Is the Product... Neither <input type="checkbox"/>		Strength: 75mg			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No		Orphan Drug Status <input type="checkbox"/>		Dosage Form: Capsule			
co-licensed? <input type="checkbox"/> No		FDA Approval Status <input type="text"/>		Product Shape: Capsule, Size 1			
latex-free? <input type="checkbox"/> Yes		Allergens Present <input type="text"/>		Product Color: Light Yellow			
preservative-free? <input type="checkbox"/> No		Country of Origin: US <input type="checkbox"/>		Product Imprint: C 712'			
correctional institution block? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes					
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS				ORDER INFORMATION			
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Anafranil®							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				PHARMACY ORDER / BILL UNIT			
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 0359746000004		Rec. sell unit to customer? 1 Bottle of 30 Capsules		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each	
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746		(Write-in, e.g. 1 Vial)		<input type="checkbox"/> Gram	
If yes, select exemption: <input type="text"/>						<input type="checkbox"/> Milliliter	
Other exemption - Write in: <input type="text"/>							
Is product repackaged? <input type="checkbox"/> No		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No		Provide source manufacturer for repackaged product: <input type="text"/>					
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA: <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION				ITEM AND PACKING INFORMATION			
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		1				00359746712303	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack						40359746712301	
<input checked="" type="checkbox"/> Case		24					
<input type="checkbox"/> Pallet							
				COST INFORMATION			
Regular Cost				WHOLESALE USE ONLY:			
Invoice Cost (WAC) (\$)		\$145.74		Vendor #:			
As of date: <input type="text"/>				Whsl. Code #:			
				Fineline Code:			

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated 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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - 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.) No
- e. Does the product contain DEHP? 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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

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? No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger No
- Cargo No
- Passenger & Cargo 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?

- No (if yes, identify method below)
- Limited Quantity
- 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

Is the Product...

- Controlled Substance? No Yes
- Controlled Substance Code
- Controlled by State(s)? No Yes
- Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No
NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:

Med Guide Required No
Limited Distribution Requirement No
Comments / Details: (For example, iPledge program?)

REMS:
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry:
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

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?

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: <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday
Class of Trade Restriction:	Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>