



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 7/12/2021

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*				
Company Name: Jubilant Cadista Pharmaceuticals Inc.		Application: ANDA		<b>a. Temperature – Indicate the USP temperature range for this product.</b>				
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		Unit of Use NDC: 3-59746-712-30-3		Is this product to be shipped to customers on ice? <input type="checkbox"/> No				
Selling Unit NDC: 59746-712-30		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No		
UDI: <input type="text"/>				<b>b. Contact for temperature excursion questions:</b>				
Description: Clomipramine Hydrochloride 75mg 30ct Capsules				Name: Customer Service				
Active Ingredient(s): Clomipramine Hydrochloride				Number: (800) 313-4623				
URL for Additional Product Information: <a href="http://www.cadista.com/products/full-product-list">www.cadista.com/products/full-product-list</a>				Group E-mail: <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a>				
Address: 207 Kiley Drive		State: MD		Address 2: <input type="text"/>				
City: Salisbury		Zip: 21801		<b>c. Special regulations for product in any states?</b>				
Key Contact: Jackie Emershaw		Email: <a href="mailto:Jackie.Emershaw@jubl.com">Jackie.Emershaw@jubl.com</a>		Special returns requirements for this product? <input type="checkbox"/> No				
Phone Number: (410) 912-3722		Fax: (215) - 443 - 9646		Protect product (unit of sale) from light? <input type="checkbox"/> No				
Product Therapeutic Classification: Antidepressant				Initial shelf life at launch (if different): <input type="text"/> Months				
				e. Shelf life: <input type="text"/> Months				
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION			ORDER INFORMATION		
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size: 30 count	<b>Unit of Sale</b>			<b>What is the NDC selling unit?</b>		
if yes, enter class # <input type="text"/>	Is the Product... Neither <input type="checkbox"/>	Strength: 75mg	<input checked="" type="checkbox"/> Bottle	1 bottle of 30 capsules			Minimum order quantity? <input type="checkbox"/> Yes	
if yes, list NDCs of product kit? <input type="text"/>	Orphan Drug Status <input type="checkbox"/>	Dosage Form: CAPSULES	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)				
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: Capsule, Size 1	<input type="checkbox"/> Ampule					
co-licensed? <input type="checkbox"/> No	Allergens Present <input type="text"/>	Product Color: Light Yellow	<input type="checkbox"/> Glass					
latex-free? <input type="checkbox"/> Yes	Country of Origin: US <input type="checkbox"/>	Product Imprint: C / 712	<input type="checkbox"/> Tube					
preservative-free? <input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		<input type="checkbox"/> Vial Liquid Sgl					
correctional institution block? <input type="checkbox"/> Yes			<input type="checkbox"/> Vial Liquid Multi					
opioid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Powder Sgl					
Cannabinoid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Power Multi					
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			<input type="checkbox"/> Other: Write In					
If Unit Dose, indicate NDC here: <input type="text"/>								
						PHARMACY ORDER / BILL UNIT		
<b>I. Orange Book Rating:</b> AB			Authorized Generic <input type="checkbox"/>			<b>Rec. sell unit to customer?</b>		
<b>II. Generic Equivalent to What Brand?:</b> Anaftranil			*If Authorized Generic, other section fields are not applicable			1 bottle of 30 capsules		
						Rx billing unit to pharmacy:		
						<input checked="" type="checkbox"/> Each		
						<input type="checkbox"/> Gram		
						<input type="checkbox"/> Milliliter		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes			GLN: 0359746000004					
Is product exempt from DSCSA? <input type="checkbox"/> No			GCP: 0359746					
If yes, select exemption: <input type="text"/>								
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								
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1				00359746712303		
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack								
<input checked="" type="checkbox"/> Case		24				40359746712301		
<input type="checkbox"/> Pallet								
COST INFORMATION				WHOLESALE USE ONLY:				
Regular Cost <input type="text"/>				Vendor #: <input type="text"/>				
Invoice Cost (WAC) (\$) <input type="text"/>				Whsl. Code #: <input type="text"/>				
As of date: <input type="text"/>				Fineline Code: <input type="text"/>				
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.								
*Please provide any additional information on page 2.			See new p. 3 for Designated Drop Ship Only.			Signature: <input type="text"/>		

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No            Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No            Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify <input type="checkbox"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug?            If yes, indicate which: <input type="checkbox"/> No <input style="width: 100%; height: 15px;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/> Waste Characteristics: <input style="width: 30%;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry?            Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b></p> <p>REMS Program Manager Name: <input style="width: 60%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively:            Wholesale distributor support: <input style="width: 60%;" type="text"/></p> <p>Provider Name: <input style="width: 60%;" type="text"/> DEA #: <input style="width: 20%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 60%;" type="text"/> NCPDP#: <input style="width: 20%;" type="text"/></p> <p>NPI #: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <p>Registry Program Contact Name: <input style="width: 60%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">RETURN INSTRUCTIONS</p> <p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No <input type="checkbox"/> Yes      Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No <input type="checkbox"/> Yes      Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No <input type="checkbox"/> Yes      If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input type="text"/>      Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<input style="width: 100%; height: 100%;" type="text"/>							



# 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 <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"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: 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"/>
Class of Trade Restriction:	
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:	
<input type="text"/>	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>