



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A212218
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Clomipramine HCl
Selling Unit NDC:	59746-0712-30
Individual Unit NDC:	
UPC:	3-59746-71230-3
CVX Code:	
MVX Code:	
Description:	Clomipramine HCl 75mg Capsule 30ct
Active Ingredient(s):	Clomipramine Hydrochloride
URL for Additional Product Information:	
Address:	207 Kiley Drive
City:	Salisbury
Key Contact:	Jackie Emershaw
Phone Number:	(410) 912-3722
Product Therapeutic Classification:	
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Customer Service
Number:	(800) 313-4623
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="text" value="Yes"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only	<input type="text" value="Direct-Ship Only"/>
Is the Product...	<input type="text" value=""/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>
If Unit Dose NDC, indicate NDC here:	<input type="text" value=""/>
Country of Origin	<input type="text" value=""/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value=""/>

PRODUCT DESCRIPTION INFORMATION	
Size:	30ct
Strength:	75mg
Dosage Form:	Capsule
Product Shape:	Opaque Capsule
Product Color:	Light Yellow & Light Yellow
Product Imprint:	C '712'

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 case of 24 bottles
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? <input type="text" value="Yes"/>
	If Yes, how many of which package type?
	<input type="text" value="24"/> Each
	<input type="text" value=""/>
	<input type="text" value=""/>
	<input type="text" value=""/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Generic Equivalent to What Brand?:	Anafranil®
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value=""/>	<input type="text" value=""/>
(Write-in, e.g. 1 Vial)	Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
GLN:	0359746000004
If Yes, was original product purchased direct from mfr?	<input type="text" value=""/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.08	1.8	3	1.8	9.72	0
Case:	2.42	11	4.25	7.5	350.625	24
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	Yes		
If not, when?	<input type="text" value=""/>		
Items aggregated?	<input type="text" value=""/>		
Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input type="checkbox"/>	1	00359746712303
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	24	40359746712301
<input type="checkbox"/> Pallet	<input type="checkbox"/>		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$145.74	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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? No
  - 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? No
  - (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or 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
- 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 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
- Controlled by State(s)? No
- ARCOS Reportable? No
- Schedule No. (inc. N for non-narcotic)
- Controlled Substance Code
- Listed Chemical (List I or II) No
  - If yes, indicate which:
- Is it a scheduled listed chemical product?

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments) No

Comments:

### SDS Hazard Classification

- |   |   |
|---|---|
| <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 |
- Aerosol Class; Identify NFPA Storage Level:

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

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

Comments / Details: (For example, iPledge program?)

**REMS:** No

REMS Program Manager Name: <input style="width: 150px;" type="text"/>	Phone: <input style="width: 100px;" type="text"/>
Supplier Manages REMS registry exclusively: <input style="width: 100px;" type="text"/>	
Wholesale distributor support: <input style="width: 100px;" type="text"/>	
Provider Name: <input style="width: 150px;" type="text"/>	DEA #: <input style="width: 100px;" type="text"/>
Site Enrollment Number assigned by Supplier: <input style="width: 150px;" type="text"/>	PCPDP #: <input style="width: 100px;" type="text"/>
	NPI #: <input style="width: 100px;" type="text"/>

Comments:

**Registry:**   
Registry Program Contact Name:  Phone:   
Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

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:

**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																																		
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 15%;"><input type="text"/></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>					b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 60%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 15%;" type="text"/> Hours <input style="width: 15%;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
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Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input style="width: 60%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 60%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 60%;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 60%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%;"><input style="width: 60%;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 60%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 60%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 60%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 60%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 60%;" type="text"/>	Phone #:	<input style="width: 60%;" type="text"/>	Fax:	<input style="width: 60%;" type="text"/>	Fax #:	<input style="width: 60%;" type="text"/>	EDI:	<input style="width: 60%;" type="text"/>														
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input style="width: 60%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 60%;" type="text"/></p> <p>Physician State License #: <input style="width: 60%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 60%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 60%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																																		
Miscellaneous Notes:																																			
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