

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

| Version 2021   |                    |                      |   |               |                         | Introduction Typ        | Post Launch Change               |                   | x   | Final Version                       |                      |               | Date:                        | 6/9/2            | 2023       |  |
|--|--------------------|----------------------|---|---------------|-------------------------|-------------------------|----------------------------------|-------------------|---|-------------------------------------|----------------------|---------------|------------------------------|------------------|------------|--|
|  |                    |                      | PRODUCT INFORMA                                     | TION          |                         |                         |                                  |                   |   | SPECIAL HAN                         | DLING AND STOP       | RAGE REQUI    | REMENTS*                     |                  |            |  |
| Company Name: Jubilant Cadista Pharmaceuticals Inc. Application:                   |                    |                      |   |               | n: ANDA                 | a, Temperatu            | re – Indica                      | ate the USP tempe | rature range for t  | this product.                       |                      |               |                              |                  |            |  |
| Application Number for NDA/AN  |                    |                      | ce):  | 212           | 2218                    |                         |                                  | airemperate       |   | ature Range                         | Controlled Room      |               | and 25 C (68                 | ° – 77° F)       |            |  |
| Medical Device Class, if applicat  |                    |                      |   |               |                         |                         |                                  |                   |   | 5                                   |                      |               |                              |                  |            |  |
| DUNS:  | 022490515          |                      |   |               |                         |                         |                                  |                   | Other Te  | emperature Range F                  | Requirement          |               |                              |                  |            |  |
| Proprietary Name (If Applicable) a   | and Established Na | ame: Clomi           | pramine HCI Capsules                                |               |                         |                         |                                  |                   | (wr   | ite in)                             |                      |               |                              |                  |            |  |
| Selling Unit NDC:  | 59746-712-30       |                      | Unit of Use NDC:                                    |               |                         |                         | -59746-712-30-3                  |                   | Notes   |                                     |                      |               |                              |                  |            |  |
| UDI  |                    |                      | CVX Code:   |               |                         | MVX Code:               |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
| Description:   | Clomipramine HC    | CI 75mg 30ct Capsule | S   |               |                         |                         |                                  |                   |   | oduct to be shipped                 |                      |               |                              | No               |            |  |
| 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 fo     | b. Contact for temperature excursion questions:<br>Name: Customer Service |                                     |                      |               |                              |                  |            |  |
| URL for Additional Product Inform<br>Address:                                      | 207 Kiley Drive    | www.cadista.co       | m/products/full-produc                              | t-list        | 1                       | Address 2:              |                                  |                   | Name:<br>Number:  |                                     |                      | (800) 313-4   |                              |                  |            |  |
| City:  | Salisbury          |                      |   |               |                         | MD Zip: 21801           |                                  |                   | Group E-mail:   |                                     |                      |               | customer.service@cadista.com |                  |            |  |
| Key Contact:   | Customer Service   |                      |   |               | Email:                  | customer.service        | _                                | 0.040 -           |   |                                     | <u>customer</u> .    | Service et    | dista.com                    |                  |            |  |
| Phone Number:  | (800) 313-4623     |                      |   |               | Fax:                    |                         |                                  |                   | gulations f   | for product in any                  | states?              |               |                              | No               |            |  |
| Product Therapeutic Classification   | n:                 | Antidepressant       |   |               | 1                       |                         |                                  |                   | Special r   | returns requirement                 | s for this product?  |               |                              | No               |            |  |
|  |                    |                      |   |               |                         |                         |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
|  | ADDITI             | IONAL PRODUCT IN     | IFORMATION  |               |                         | PRODUCT DE              | SCRIPTION INFORMATION            | d. Store prod     | d. Store product (unit of sale) upright? No                               |                                     |                      |               |                              |                  |            |  |
| The product is?  |                    |                      | Is the Product                                      | Direct-Ship C | Inly                    |                         |                                  |                   | Protect   | product (unit of sa                 | le) 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                                  |               |                         | 5126.                   |                                  | -111              | Initial sh  | nelf life at launch (i              | f different):        |               |                              |                  | Months     |  |
| a product kit?   |                    | No                   |   |               |                         | Strength:               | 75mg                             |                   |   |                                     |                      |               |                              |                  |            |  |
| if yes, list NDCs of   |                    |                      | FDA Approval Status                                 |               |                         | J. J. J.                | 0                                |                   |   |                                     | ORDER INFORM         | MATION        |                              |                  |            |  |
| component parts<br>reverse numbered?   |                    | No                   |   |               |                         | Dosage Form:            | Capsule                          |                   | Unit of S   | Sala                                |                      | What is the   | NDC selling                  | unit?            |            |  |
| co-licensed?   |                    | No                   | Allergens Present                                   |               |                         |                         |                                  |                   |   | Bottle                              |                      | 1 Bottle of 3 |                              | unit:            |            |  |
| latex-free?  |                    | Yes                  | Allergens Tresent                                   |               |                         |                         | Capsule, Size 1                  |                   |   | Box/Carton                          |                      |               | g. 1 Box of 1                | ) Vials)         |            |  |
| preservative-free?   |                    | No                   |   |               |                         | Product Shape           |                                  |                   |   | Ampule                              |                      |               | 5                            | ,                |            |  |
| correctional institution block?  |                    | Yes                  |   |               |                         | Product Color:          | Light Yellow                     |                   |   | Glass                               |                      | Minimum o     | rder quantity                | ?                | Yes        |  |
| opioid?  |                    | No                   |   | -             |                         | Froduct Color.          |                                  | _                 |   | Tube                                |                      |               |                              |                  |            |  |
| Cannabinoid?   |                    | No                   | Country of Origin                                   | US            |                         | Product Imprin          | C 712'                           |                   |   | Vial Liquid Sgl                     |                      |               |                              |                  |            |  |
| If Unit Dose, is item bar coded to u   | unit dose for      |                      |   |               |                         | •                       |                                  |                   |   | Vial Liquid Multi                   |                      |               | many of whi                  | ch package t     | type?      |  |
| hospital scanning?<br>If Unit Dose, indicate NDC here:                             |                    |                      | Is this product covered u<br>Trade Agreements Act ( |               | Vee                     |                         |                                  |                   |   | Vial Powder Sql<br>Vial Power Multi |                      | 24            | Each<br>Inner/Carton         | /Deels           |            |  |
| Il Unit Dose, Indicate NDC here.   |                    |                      | Trade Agreements Act (                              | TAA)?         | Yes                     |                         |                                  |                   |   | Other: Write In                     |                      |               | Case                         | Pack             |            |  |
| FOR GENERIC DRUG PRODUCTS  |                    |                      |   |               |                         |                         |                                  |                   |   | Ouse                                |                      |               |                              |                  |            |  |
|  |                    |                      |   |               |                         |                         |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
|  |                    |                      |   |               | Au                      | uthorized Generic *     | If Authorized Generic, other     |                   |   | PH                                  | ARMACY ORDER         | R / BILL UNIT |                              |                  |            |  |
| I. Orange Book Rating:   | AB                 |                      |   |               | ·                       | s                       | ection fields are not applicable | Rec. sell unit    | to custon   | ner?                                |                      | Rx billing u  | nit to pharma                | acv:             |            |  |
| II. Generic Equivalent to What Brand?: Anafranil®                                  |                    |                      |   | 1 B(          | 1 Bottle of 30 Capsules |                         |                                  |                   | x Each  |                                     |                      |               |                              |                  |            |  |
|  |                    |                      |   |               |                         | (Write-in, e.g. 1 Vial) |                                  |                   | 1   | Gram                                |                      |               |                              |                  |            |  |
|  |                    | DRUG SUPP            | LY CHAIN SECURITY ACT (                             | (DSCSA) INFOR | MATION                  |                         |                                  |                   |   |                                     |                      |               | Milliliter                   |                  |            |  |
|  | tion of mounts i   |                      | Yoo   |               |                         | 0359746000004           |                                  |                   | _   | 177-11                              | AND PACKING I        | NEODMATIO     | N                            |                  |            |  |
| Does supplier meet DSCSA definit<br>Is product exempt from DSCSA?                  | tion of manufactu  | rer?                 | Yes   | _             | GLN:                    | 0359746000004           |                                  |                   |   | IIEN                                | AND PACKING I        | NFORMATIO     | N                            |                  |            |  |
|  |                    |                      | 110   |               |                         |                         |                                  |                   |   |                                     | D'                   | iana (110     | -4- )                        |                  |            |  |
| If yes, select exemption:  |                    |                      |   |               | GCP:                    | 0359746                 |                                  |                   |   | Weight Lbs.                         |                      | ions (US msr  |                              | Volume<br>(Cubo) | Saleable # |  |
| Other exemption - Write in:<br>Is product repackaged?                              |                    |                      | No  |               | If yos was a            | riginal product purch   | hase                             | Item/Each:        |   |                                     | Depth                | Width         | Height                       | (Cube)           | Pieces     |  |
| Is product sold by manufacturer's  | exclusive distrib  | utor?                | No  | -             | direct from n           |                         | aseu                             | nem/Each.         |   | 0.08                                | 1.8                  | 1.8           | 3                            | 9.72             | 1          |  |
| Has FDA granted waiver/exception   |                    |                      | No  | -             |                         | ce manufacturer for r   | repackaged product               | Box/Carton/E      | Bundle/   |                                     |                      |               |                              | 0.00             |            |  |
| If yes, attach documentation from  |                    | L                    |   |               |                         |                         |                                  | Inner Pack:       |   |                                     |                      |               |                              | 0.00             |            |  |
|  |                    |                      |   |               |                         |                         |                                  | Case:             |   | 2.42                                | 11                   | 7.5           | 4.25                         | 350.63           | 24         |  |
|  |                    | GT                   | IN AND HIBCC PRODUCT I                              | NFORMATION    |                         |                         |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
| Saleable Unit of Measure   |                    |                      |   |               |                         |                         |                                  | Pallet:           |   |                                     |                      |               |                              | 0.00             |            |  |
| X Item/Each  | 5                  | Saleable Quantity    | HIBCC   |               |                         | IN-14<br>359746712303   | Unit of Use GTIN-14              |                   |   |                                     |                      |               |                              |                  |            |  |
| Box/Carton/Bundle/Inner Pack   |                    |                      |   |               |                         |                         | COST INFORMATION                 |                   |   |                                     | WHOLESALER USE ONLY: |               |                              |                  |            |  |
| X Case   |                    |                      |   |               |                         |                         |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
| Pallet   |                    |                      |   |               | 1                       |                         |                                  | Regular Cost      | t   |                                     |                      | Vendor #:     |                              |                  |            |  |
|  |                    |                      |   |               |                         |                         |                                  | Invoice Cost      |   |                                     | \$145.74             | Whsl. Code    |                              |                  |            |  |
|  | _                  |                      |   |               |                         |                         |                                  |                   |   |                                     |                      | Fineline Co   | de:                          |                  |            |  |
|  | -                  |                      |   |               |                         |                         |                                  | As of date:       |   |                                     |                      |               |                              |                  |            |  |
|  |                    |                      |   |               |                         |                         |                                  |                   |   |                                     |                      |               |                              |                  |            |  |
| <u> </u>   |                    |                      |   |               | (C) as a i              | ad latter DAOKAOS "     |                                  |                   |   |                                     |                      | +             |                              |                  |            |  |
| *Diseas provide only additional laf  |                    | 2                    | Attach copy of SAFETY DA                            | ATA SHEET (SD | or non haza             |                         | SERT, LABEL AND PHOTO O          | F PRODUCT PACK    |   |                                     |                      |               |                              |                  |            |  |
| *Please provide any additional info  | ormation on page   | 2.                   |   |               |                         | See new p. 3 for De     | esignated Drop Ship Only.        |                   | Signatur  | re:                                 |                      |               |                              |                  |            |  |

## **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):<br>a. Cytotoxic?<br>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?<br>Is the product a CA Prop 65 carcinogen?<br>Is the product a CA Prop 65 reproductive toxicant?<br>Does the product label bear a CA Prop 65 warning?<br>c. Contact Hazard?<br>d. Does this product require special clean-up instructions?<br>(If yes, attach SDS with special instructions.)<br>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?<br>(if yes, answer a-e below and provide SDS)<br>a. UN/Identification Number<br>b. Proper Shipping Name<br>c. DOT Hazard Class<br>d. Packing Group<br>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?<br>(if yes, answer a-e below and provide SDS)<br>a. UN/Identification Number<br>b. Proper Shipping Name<br>c. DOT Hazard Class<br>d. Packing Group<br>e. Inhalation Hazard?<br>Is the product restricted for air shipment? If so, indicate restriction:<br>Passenger<br>Cargo<br>Passenger & Cargo<br>Is this a reportable quantity? No<br>RQ Threshold:<br>Is this a marine pollutant? No<br>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br>No<br>(if yes, identify method below)<br>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<br>Small Quantity (49 CFR 173.4)<br>Special Permit; DOT-SP<br>Special Provision (listed in Column 7 of 49 CFR 172.101);<br>SP#<br>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<br>Restricted to retail pharmacy only:<br>Restricted to hospital, clinics, and physician offices only:<br>Restricted from US territories? (explain in comments)<br>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:<br>Is product returnable for credit:<br>URL/Link to returns policy:<br>Special regulations or returns requirements for this product in certain states?<br>If so, which states? Other requirements? Comments?   |
| Miscellaneous Notes:  |  |
|   | ADDITIONAL INFORMATION   |
|   | Is product order for scheduled patient procedure?  |