



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

Version 2021

Introduction Type:  New Product  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): 079132				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: Lamotrigine Tablets		Unit of Use NDC: 3-59746-248-60-4		Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 59746-248-60		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: Lamotrigine 200mg 60ct Tablet				Name: Customer Service			
Active Ingredient(s): Lamotrigine				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		Address 2: <input type="text"/>		<b>c. Special regulations for product in any states?</b>			
City: Salisbury		State: MD Zip: 21801		Special returns requirements for this product? <input type="checkbox"/> No			
Key Contact: Jackie Emershaw		Email: Jackie.Emershaw@jubl.com		<b>d. Store product (unit of sale) upright?</b>			
Phone Number: (410) 912-3722		Fax: (215) - 443 - 9646		Protect product (unit of sale) from light? <input type="checkbox"/> No			
Product Therapeutic Classification: Antiepileptic				<b>e. Shelf life:</b>			
				Initial shelf life at launch (if different): <input type="text"/> Months			
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>			
The product is? a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/> Neither <input type="checkbox"/>		Size: 60 count			
if yes, enter class # <input type="text"/>		Orphan Drug Status <input type="checkbox"/>		Strength: 200mg			
if yes, list NDCs of component parts <input type="text"/>		FDA Approval Status <input type="text"/>		Dosage Form: TABLET			
reverse numbered? <input type="checkbox"/> No		Allergens Present <input type="text"/>		Product Shape: Round			
co-licensed? <input type="checkbox"/> No		Country of Origin: US		Product Color: White			
latex-free? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		Product Imprint: J 248			
preservative-free? <input type="checkbox"/> No							
correctional institution block? <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"/>							
<b>FOR GENERIC DRUG PRODUCTS</b>				<b>ORDER INFORMATION</b>			
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable		Unit of Sale		What is the NDC selling unit?	
II. Generic Equivalent to What Brand?: Lamictal				<input checked="" type="checkbox"/> Bottle		1 bottles of 60 tablets	
				<input type="checkbox"/> Box/Carton		(Write-in, e.g. 1 Box of 10 Vials)	
				<input type="checkbox"/> Ampule			
				<input type="checkbox"/> Glass		Minimum order quantity? <input type="checkbox"/> Yes	
				<input type="checkbox"/> Tube			
				<input type="checkbox"/> Vial Liquid Sgl			
				<input type="checkbox"/> Vial Liquid Multi		If Yes, how many of which package type?	
				<input type="checkbox"/> Vial Powder Sgl		48 Each	
				<input type="checkbox"/> Vial Power Multi		Inner/ Carton/ Pack	
				<input type="checkbox"/> Other: Write In		Case	
<b>PHARMACY ORDER / BILL UNIT</b>				<b>ITEM AND PACKING INFORMATION</b>			
Rec. sell unit to customer? 1 bottles of 60 tablets		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each		Weight Lbs.		Dimensions (US msmts.)	
(Write-in, e.g. 1 Vial)		<input type="checkbox"/> Gram		Depth		Width	
		<input type="checkbox"/> Milliliter		Height		Volume (Cube)	
				Saleable # Pieces			
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>				Item/Each: 0.15 1.9 1.9 4 14.44 1			
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 0359746000004		Box/Carton/Bundle/Inner Pack: 9.25 16.25 12 4.5 877.50 48		Pallet: 0.00	
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA. <input type="text"/>							
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>				<b>COST INFORMATION</b>			
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		1				Unit of Use GTIN-14	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack						00359746248604	
<input checked="" type="checkbox"/> Case		48				40359746248602	
<input type="checkbox"/> Pallet							
<b>WHOLESALE USE ONLY:</b>				Regular Cost			
Invoice Cost (WAC) (\$)		\$6.27		Vendor #:			
As of date: <input type="text"/>				Whsl. Code #:			
				Fineline Code:			
				Signature: <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:

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For Designated Drop Ship Only Products, Please Use Page 3

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%; border: 1px solid black;" 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 <input type="checkbox"/> No</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:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>