



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

Version 2021

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*				
Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.		Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>		
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="040659"/>				Other Temperature Range Requirement (write in): <input type="text"/>		Notes: <input type="text"/>		
Medical Device Class, if applicable: <input type="text"/>				Is this product to be shipped to customers on ice? <input type="text" value="No"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>		
DUNS: <input type="text" value="022490515"/>				b. Contact for temperature excursion questions:		Name: <input type="text" value="Customer Service"/>		
Proprietary Name (if Applicable) and Established Name: <input type="text" value="Meclizine HCl Tablets"/>		Unit of Use NDC: <input type="text" value="3-59746-122-06-5"/>		Number: <input type="text" value="(800) 313-4623"/>		Group E-mail: <input type="text" value="customer.service@cadista.com"/>		
Selling Unit NDC: <input type="text" value="59746-122-06"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>		c. Special regulations for product in any states? <input type="text" value="No"/>		
Description: <input type="text" value="Meclizine Hydrochloride 12.5mg 100ct Tablet"/>				Special returns requirements for this product? <input type="text" value="No"/>		d. Store product (unit of sale) upright? <input type="text" value="No"/>		
Active Ingredient(s): <input type="text" value="Meclizine Hydrochloride"/>				Protect product (unit of sale) from light? <input type="text" value="No"/>		e. Shelf life: <input type="text" value="24"/> Months		
URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/>				Initial shelf life at launch (if different): <input type="text"/>		Months		
Address: <input type="text" value="207 Kiley Drive"/>		Address 2: <input type="text"/>						
City: <input type="text" value="Salisbury"/>		State: <input type="text" value="MD"/>		Zip: <input type="text" value="21801"/>				
Key Contact: <input type="text" value="Jackie Emershaw"/>		Email: <input type="text" value="Jackie.Emershaw@jubl.com"/>						
Phone Number: <input type="text" value="(410) 912-3722"/>		Fax: <input type="text" value="(215) - 443 - 9646"/>						
Product Therapeutic Classification: <input type="text" value="Antinausea"/>								
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION				
The product is? a legend device? <input type="text" value="No"/>	Is the Product... Direct-Ship Only <input type="text"/>	Size: <input type="text" value="100 count"/>					Unit of Sale: <input checked="" type="checkbox"/> Bottle	
if yes, enter class # a product kit? <input type="text"/>	Is the Product... Neither <input type="text"/>	Strength: <input type="text" value="12.5mg"/>					What is the NDC selling unit? <input type="text" value="1 bottle of 100 tablets"/>	
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	Orphan Drug Status: <input type="text"/>	Dosage Form: <input type="text" value="TABLETS"/>					(Write-in, e.g. 1 Box of 10 Vials)	
co-licensed? <input type="text" value="No"/>	FDA Approval Status: <input type="text"/>	Product Shape: <input type="text" value="Oval"/>					Minimum order quantity? <input type="text" value="Yes"/>	
latex-free? <input type="text" value="Yes"/>	Allergens Present: <input type="text"/>	Product Color: <input type="text" value="Blue"/>					If Yes, how many of which package type?	
preservative-free? <input type="text" value="No"/>	Country of Origin: <input type="text" value="US"/>	Product Imprint: <input type="text" value="TL 122"/>					<input type="text" value="24"/> Each	
correctional institution block? <input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>						<input type="text"/>	
opioid? <input type="text" value="No"/>							Inner/ Carton/ Pack	
Cannabinoid? <input type="text" value="No"/>							Case	
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>								
If Unit Dose, indicate NDC here: <input type="text"/>								
FOR GENERIC DRUG PRODUCTS								
I. Orange Book Rating: <input type="text" value="AA"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable				
II. Generic Equivalent to What Brand?: <input type="text" value="Antivert"/>								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0359746000004"/>						
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text" value="0359746"/>						
If yes, select exemption: <input type="text"/>								
Other exemption - Write in: <input type="text"/>								
Is product repackaged? <input type="text" value="No"/>		If yes, was original product purchased direct from mfr? <input type="text"/>						
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>		Provide source manufacturer for repackaged product: <input type="text"/>						
Has FDA granted waiver/exception/exemption for product? <input type="text" value="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	<input type="text" value="1"/>		<input type="text" value="00359746122065"/>					
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack								
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>		<input type="text" value="40359746122063"/>					
<input type="checkbox"/> Pallet								
COST INFORMATION				WHOLESALE USE ONLY:				
Regular Cost		Invoice Cost (WAC) (\$)		<input type="text" value="\$17.18"/>		Vendor #: <input type="text"/>		
As of date: <input type="text"/>						Whsl. Code #: <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:



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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
- 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  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  No
- 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  No

NFPA Storage Level:

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input 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>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></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 type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input 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 type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input 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>