

PRODUCT INFORMATION			
Company Name:		Jubilant Cadista Pharmaceuticals Inc.	Application:
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		201845	ANDA
Medical Device Class, if applicable:			
DUNS:	022490515		
Proprietary Name (If Applicable) and Established Name:		Losartan - HCTZ Tablets	
Selling Unit NDC:	59746-339-90	Unit of Use NDC:	UPC: 3-59746-339-90-6
UDI		CVX Code:	MVX Code:
Description:	Losartan Potassium - Hydrochlorothiazide 100-25mg 90ct Tablet		
Active Ingredient(s):	Losartan Potassium; Hydrochlorothiazide		
URL for Additional Product Information: www.cadista.com/products/full-product-list			
Address:	207 Kiley Drive	Address 2:	
City:	Salisbury	State:	MD Zip: 21801
Key Contact:	Jackie Emershaw	Email:	Jackie.Emershaw@jubl.com
Phone Number:	(410) 912-3722	Fax:	(215) - 443 - 9646
Product Therapeutic Classification:	Antihypertensive		

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	No	Is the Product... Neither	
if yes, enter class #		Orphan Drug Status	
a product kit?	No		
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	No		
correctional institution block?	Yes		
opioid?	No	Country of Origin	US
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	Yes
If Unit Dose, indicate NDC here:			

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Hyzaar
	Authorized Generic *If Authorized Generic, other section fields are not applicable

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
GLN:	0359746000004
GCP:	0359746
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
X Item/Each	1		00359746339906	
X Box/Carton/Bundle/Inner Pack				
X Case	24		40359746339904	
X Pallet				

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)					
Notes					
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:		customer.service@cadista.com			
c. Special regulations for product in any states?					
Special returns requirements for this product?		No			
d. Store product (unit of sale) upright?					
Protect product (unit of sale) from light?		No			
e. Shelf life:					
Initial shelf life at launch (if different):		24 Months			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
X Bottle	1 bottle of 90 tablets
Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
Ampule	
Glass	
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	
Vial Powder Sgl	
Vial Power Multi	
Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	24 Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 90 tablets	X Each
(Write-in, e.g. 1 Vial)	Gram
	Milliliter

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume	Saleable Pieces
		Depth	Width	Height	(Cube)	
Item/Each:	0.18	1.9	1.9	4	14.44	1
Box/Carton/Bundle/ Inner Pack:					0.00	
Case:	5.21	11.5	7.75	5	445.63	24
Pallet:					0.00	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$26.10	Whst. Code #:	
As of date:		Fineline Code:	

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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

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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?	<input type="checkbox"/>	No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/>	No	
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	
c. Contact Hazard?	<input type="checkbox"/>	No	
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/>	No	
e. Does the product contain DEHP?	<input type="checkbox"/>	No	
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)		<input type="checkbox"/> No	
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	<input type="checkbox"/>	No	
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)		<input type="checkbox"/> No	
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	<input type="checkbox"/>	No	
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity?	<input type="checkbox"/> No		
RQ Threshold:			
Is this a marine pollutant?	<input type="checkbox"/> No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No	(if yes, identify method below)		
<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#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
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:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

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
Does the product have an Aerosol class? If yes, identify <input type="checkbox"/> No	
NFPA Storage Level: <input type="text"/>	
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<input type="checkbox"/> No
If Yes, is it managed with a pharmacy registry?	<input type="checkbox"/>
Website URL:	<input type="text"/>
Med Guide Required	<input type="checkbox"/> No
Limited Distribution Requirement	<input type="checkbox"/> No
Comments / Details: (For example, iPledge program?)	<input type="text"/>
REMS:	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/>
Wholesale distributor support:	<input type="checkbox"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
Registry:	
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product 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"/>



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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>Purchase order daily receipt cut off time by supplier</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>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <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
<input type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>