

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	12/24/	/2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Application:	ANDA	a. Temperature -	- Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 204316				NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room -		and 25 C (68°	– 77° F)	
Medical Device Class, if applicab									,					
DUNS:	11-856-3719							Ot	ther Temperature Range F	equirement				
Proprietary Name (If Applicable) a		ame: Quetiapi	ine Tablets, USP 25 mg						(write in)					
Selling Unit NDC:	31722-764-01		Unit of Use NDC:				22764018	No	otes					
UDI			CVX Code:			MVX Code:								
Description:	Quetiapine Table	ts, USP 25 mg						Is	this product to be shipped	to customers on ic	e?		No	
								Is	this product to be shipped	to customers on d	ry ice?		No	ı
Active Ingredient(s):		Quetiapine fumarate,	USP							_				
URL for Additional Product Inform									mperature excursion que	estions:	Soma Raju			
Address:	800 Centennial A	www.camberpharma.com				Address 2:			ame: umber:		732-529-042	3		
City:	Piscataway					: 08854		roup E-mail:		somaraju@h				
Key Contact:	Customer Service	e	Email: customerservice@camberpharma.com						Toup E mail.		<u>oomaraja on</u>	01010404.0011		
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regula	ations for product in any	states?			No	
Product Therapeutic Classification	1:	Atypical antipsychotic	c					Sp	pecial returns requirement	for this product?			No	
•														
	ADDIT	IONAL PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly			Pr	rotect product (unit of sa	le) from light?		i	No	
a legend device?		No	Is the Product	Neither	,	Size:	100 ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		In	nitial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	25 mg							
if yes, list NDCs of			FDA Approval Status			J				ORDER INFORM	ATION			
component parts		lat.				Dosage Form:	Film-coated tablet	116	nit of Sale		What is the	NDC colling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present					U	x Bottle		1 Bottle of 10		JIIIL?	
latex-free?		Yes					Round, biconvex		Box/Carton			g. 1 Box of 10	Vials)	
preservative-free?		Yes	Dairy, Lactose, A	Animal Product	s	Product Shape:	rtouria, bioditrox		Ampule		(**************************************	g. 1 Dox 01 10	viaio)	
correctional institution block?		No				Product Color:	Peach		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with '44' on one side and 'I' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					1 Todaot Impilita	and 'I' on the other side		Vial Liquid Multi		If Yes, how		h package t	ype?
hospital scanning?			Is this product covered un						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton/ Case	Pack	
			FOR GENERIC DRUG PRO	PLIOTO					Other, write in			Case		
			FOR GENERIC DRUG PRO	DDUCIS										
				Г	Διι	thorized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I Oranga Baali Batings	AB				7.0		on fields are not applicable	Rec. sell unit to customer?				Rx billing unit to pharmacy:		
I. Orange Book Rating: II. Generic Equivalent to What Brar		Seroquel						Rec. Sell unit to	customerr		KX billing ui	Each	cy:	
ii. Generic Equivalent to What Brai	iu:.	Octoquei						(Write-in, e.g. 1 \				Gram		
									Vial)					
		DRUG SUPPLY	CHAIN SECURITY ACT (D	OSCSA) INFORI	MATION			HCPCS J-Code:	Vial)			Milliliter		
		DRUG SUPPLY	CHAIN SECURITY ACT (C	OSCSA) INFORI	MATION									
Does supplier meet DSCSA definit	ion of manufactu		Yes		MATION GLN:	0331722498975				AND PACKING IN	IFORMATION			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	ion of manufactu		·			0331722498975				AND PACKING IN	IFORMATION			
	ion of manufactu		Yes			0331722498975			ITEM		IFORMATION			Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ion of manufactu		Yes No		GLN: GCP:			HCPCS J-Code:					Volume (Cube)	Saleable # Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		irer?	Yes No		GLN: GCP: If yes, was or	iginal product purchase	d		ITEM	Dimensio	ons (US msm	ts.)		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distrib	utor?	Yes No No Yes		GLN: GCP: If yes, was or direct from m	iginal product purchase		HCPCS J-Code:	Weight Lbs.	Dimensio Depth	ons (US msm Width	ts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	exclusive distrib Vexemption for p	utor?	Yes No		GLN: GCP: If yes, was or direct from m	iginal product purchase		HCPCS J-Code: Item/Each: Box/Carton/Bund	Weight Lbs.	Dimensio Depth	ons (US msm Width	ts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distrib Vexemption for p	utor?	Yes No No Yes		GLN: GCP: If yes, was or direct from m	iginal product purchase		Item/Each: Box/Carton/Bunclinner Pack:	Weight Lbs. 0.08	Dimension Depth 1.55	ons (US msm Width 1.55	ts.) Height	(Cube) 6.01	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron	exclusive distrib v/exemption for p n FDA. RFID tag(Y/N)	utor? roduct? GTIN Saleable Quantity	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide sourd	iginal product purchase fr? se manufacturer for repa	ickaged product	Item/Each: Box/Carton/Bunc Inner Pack: Case:	Weight Lbs. 0.08	Dimension Depth 1.55	ons (US msm Width 1.55	ts.) Height	(Cube) 6.01	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib n/exemption for p n FDA.	utor? oroduct? GTIN Saleable	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide sourd	iginal product purchase fr? ce manufacturer for repa	ickaged product	Item/Each: Box/Carton/Bunc Inner Pack: Case:	Weight Lbs. 0.08 dle/ 2.1	Dimension Depth 1.55	ons (US msm Width 1.55	ts.) Height 2.5	(Cube) 6.01 263.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib Vexemption for p n FDA. RFID tag(Y/N)	utor? croduct? GTIN Saleable Quantity 1	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product purchase fr? De manufacturer for repair N-14	ickaged product	Item/Each: Box/Carton/Bunc Inner Pack: Case:	Weight Lbs. 0.08	Dimension Depth 1.55	ons (US msm Width 1.55	ts.) Height 2.5	(Cube) 6.01	Pieces 1 24
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib Vexemption for p n FDA. RFID tag(Y/N)	utor? croduct? GTIN Saleable Quantity 1	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product purchase fr? De manufacturer for repair N-14	ickaged product	Item/Each: Box/Carton/Bune Inner Pack: Case: Pallet:	Weight Lbs. 0.08 dle/ 2.1 COST INFORMATION	Dimension Depth 1.55	ons (US msm Width 1.55 6.75	ts.) Height 2.5 4	(Cube) 6.01 263.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib Vexemption for p n FDA. RFID tag(Y/N)	utor? croduct? GTIN Saleable Quantity 1	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product purchase fr? De manufacturer for repair N-14	ickaged product	Item/Each: Box/Carton/BuneInner Pack: Case: Pallet:	Weight Lbs. 0.08 dle/ 2.1 COST INFORMATION	Dimension Depth 1.55	ons (US msm Width 1.55 6.75	ts.) Height 2.5 4 WHOLESALE	(Cube) 6.01 263.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib Vexemption for p n FDA. RFID tag(Y/N)	utor? croduct? GTIN Saleable Quantity 1	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product purchase fr? De manufacturer for repair N-14	ickaged product	Item/Each: Box/Carton/Bune Inner Pack: Case: Pallet:	Weight Lbs. 0.08 dle/ 2.1 COST INFORMATION	Dimension Depth 1.55	vendor #: Whell Code	ts.) Height 2.5 4 WHOLESALE	(Cube) 6.01 263.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib Vexemption for p n FDA. RFID tag(Y/N)	utor? croduct? GTIN Saleable Quantity 1	Yes No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product purchase fr? De manufacturer for repair N-14	ickaged product	Item/Each: Box/Carton/Bundinner Pack: Case: Pallet: Regular Cost Invoice Cost (W/	Weight Lbs. 0.08 dle/ 2.1 COST INFORMATION AC) (\$)	Dimension Depth 1.55	vendor #: Whell Code	ts.) Height 2.5 4 WHOLESALE	(Cube) 6.01 263.25	Pieces 1 24
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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, indicate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	Tractification Tradition administration						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
, ,	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS						
	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?	Website UKL.						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	Comments						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No	·						
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only: No	140						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:						



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

Version 2024

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: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is 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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?