

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

						Introduction 1	Type:	New Item		x Final Version			Date:	6/10/	2024		
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*				
Company Name:	Camber Pharmaceuticals,	Inc				Applica	tion:	ANDA	a Temperatu	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN			ce).	207	7419	740000		7.11.571	d. remperatu	Temperature Range	Controlled Room		and 25 C (68	° – 77° F)			
Medical Device Class, if applical		.,(romporataro rtango							
DUNS:	11-856-3719								-	Other Temperature Range	Requirement						
Proprietary Name (If Applicable) a	and Established Name:	Oxycod	done and Acetaminophen Ta	ablets, USP 7.5	mg/325 mg					(write in)							
Selling Unit NDC:	31722-950-01		Unit of Use NDC:			UPC:	331722	2950015		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Oxycodone and Acetamine	ophen Tablets	s. USP 7.5 ma/325 ma							Is this product to be shipped	d to customers on id	ce?		No			
Is this product to be shipped to customers on dry ice? No									No								
Active Ingredient(s): Oxycodone hydrochloride, USP, acetaminophen, USP																	
b. Contact for temperature excursion questions:																	
URL for Additional Product Inform									Name: Soma Raju								
Address:		Centennial Ave, Suite 1			01-1-1	Address 2:		00054	Number: 732-529-0423								
City:	Piscataway Customer Service				NJ		08854	Group E-mail: somaraju@heterousa.com				1					
Key Contact: Phone Number:	1-866-827-3647				customerservice@camberpharma.com 732-562-8788			c Special rea			*Yes						
Product Therapeutic Classification	Comi		agonist, and non-opioid, non-salicylate a	analgesic and	l ux.	102 002 0100	132-302-6166			ulations for product in any Special returns requiremen				*Yes			
Froduct Therapeutic Classificatio	antip	retic								Special returns requiremen	is for this product?			res			
	ADDITIONAL PI	RODUCT INF	ORMATION			PRODUCT	DESCRIE	PTION INFORMATION	d Store prod	uct (unit of sale) upright?				No			
T	ADDITIONALTI	KODOOT IIVI		Direct Ohio C	No.	TRODUCT	DEGGINI	THOR IN ORMATION	u. Store prou								
The product is? a legend device?	No		Is the Product	Direct-Ship C Neither	Jrily			100 ct	e. Shelf life:	Protect product (unit of s	ale) from light?			No 24	Months		
if yes, enter class #	INO		Orphan Drug Status	Iveitriei		Size:		100 Ct	e. Sileli ille.	Initial shelf life at launch (ife at launch (if different):				Months		
a product kit?	No		Orphan Drug Glalas				-	7.5 mg/325 mg		initial shell life at launon (ii diiiciciity.				Months		
if yes, list NDCs of	1.0		FDA Approval Status			Strength:		7.0 mg/020 mg			ORDER INFORM	ATION					
component parts						Dosage For	Ē	Tablet									
reverse numbered?	No					Dosage For	····			Unit of Sale		What is the	NDC selling	unit?			
co-licensed?	No		Allergens Present							x Bottle		1 Bottle of 1					
latex-free?	Yes		Dve. Corn. A	Icohol, Animal		Product Shape: Capsule				Box/Carton			g. 1 Box of 1) Vials)			
preservative-free?	Yes					·				Ampule							
correctional institution block?	No					Product Col	lor:	White to off-white		Glass		Minimum o	rder quantity	?	Yes		
opioid? Cannabinoid?	Yes No		Country of Origin	USA			-	Debossed with 'T 193' on one		Tube Vial Liquid Sgl							
If Unit Dose, is item bar coded to u			Country of Origin	USA		Product Imp		side and plain on other side		Vial Liquid Multi		If Voc how	many of whi	ch nackado	tvno2		
hospital scanning?	Till dose for		Is this product covered u	inder the									Each	JII package	type:		
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes					Inner/Carton	/Pack						
				•						Other: Write In			Case				
			FOR GENERIC DRUG PRO	ODUCTS													
					Aut	horized Generic	*If Auth	norized Generic, other		PH	ARMACY ORDER	BILL UNIT					
I. Orange Book Rating:						section fields are not applicable						Rx billing unit to pharmacy:					
							section	i ileius are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm		Each		
II. Generic Equivalent to What Bra	AA Percoo	et					section	i fields are not applicable	Rec. sell unit	to customer?	1	Rx billing u		acy.			
II. Generic Equivalent to What Bra	and?: Percoo						section	i fields are not applicable	Rec. sell unit (Write-in, e.g.			Rx billing u	Each Gram	асу.			
II. Generic Equivalent to What Bra	and?: Percoo		/ CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION		section	Trielos are not applicable				Rx billing u	Each	acy.			
	Percoo		·					meios are not applicable		1 Vial)			Each Gram Milliliter				
Does supplier meet DSCSA defini	Percoo		Yes		MATION GLN:	0860000397957		meids are not applicable		1 Vial)	AND PACKING IN		Each Gram Milliliter	acy.			
Does supplier meet DSCSA defini	Percoo		·		GLN:	0860000397957		metas are not applicable		1 Vial)		IFORMATION	Each Gram Milliliter				
Does supplier meet DSCSA defining product exempt from DSCSA? If yes, select exemption:	Percoo		Yes			0860000397957		neius are nut applicable		1 Vial)	Dimensio	IFORMATION	Each Gram Milliliter	Volume	Saleable #		
Does supplier meet DSCSA definits product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	Percoo		Yes No		GLN: GCP:			neids are not applicable	(Write-in, e.g.	1 Vial)		IFORMATION	Each Gram Milliliter		Saleable #		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DR		Yes No		GLN: GCP: If yes, was or	ginal product		neids are not applicable		1 Vial)	Dimensio	IFORMATION	Each Gram Milliliter	Volume			
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ition of manufacturer?	RUG SUPPLY	Yes No No Yes		GLN: GCP: If yes, was or purchased di	ginal product			(Write-in, e.g.	1 Vial) Weight Lbs. 0.14	Dimensio Depth	DONE (US men	Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces		
Does supplier meet DSCSA defining 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	percocontrol perco	RUG SUPPLY	Yes No		GLN: GCP: If yes, was or purchased di	ginal product			(Write-in, e.g.	1 Vial) Weight Lbs. 0.14	Dimensio Depth	DONE (US men	Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	percocontrol perco	RUG SUPPLY	Yes No No Yes No		GLN: GCP: If yes, was or purchased di	ginal product			(Write-in, e.g.	Weight Lbs. 0.14	Dimension Depth 1.84	pns (US msn Width	Each Gram Milliliter Muts.) Height 3.23	Volume (Cube) 10.86	Pieces 1		
Does supplier meet DSCSA defining 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	percocontrol perco	RUG SUPPLY	Yes No No Yes		GLN: GCP: If yes, was or purchased di	ginal product			(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack:	1 Vial) Weight Lbs. 0.14	Dimensio Depth	DONE (US men	Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro	percocondition of manufacturer? s exclusive distributor? n/exemption for product? m FDA.	RUG SUPPLY	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack:	Weight Lbs. 0.14	Dimension Depth 1.84	pns (US msn Width	Each Gram Milliliter Muts.) Height 3.23	Volume (Cube) 10.86	Pieces 1		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro	ition of manufacturer? s exclusive distributor? n/exemption for product? m FDA.	GTIN Quantity	Yes No No Yes No		GLN: GCP: If yes, was or purchased di Provide source	iginal product rect from mfr? se manufacturer f			(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.14	Dimension Depth 1.84	pns (US msn Width	Each Gram Milliliter Muts.) Height 3.23	Volume (Cube) 10.86	Pieces 1		
Does supplier meet DSCSA definits product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	percocondition of manufacturer? s exclusive distributor? n/exemption for product? m FDA.	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.14 undle/ 3.11	Dimension Depth 1.84	IFORMATION Ons (US msn Width 1.84	Each Gram Milliliter	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.14	Dimension Depth 1.84	IFORMATION Ons (US msn Width 1.84	Each Gram Milliliter Muts.) Height 3.23	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BowCarton/Bundle/Inner Pack X Case	ition of manufacturer? s exclusive distributor? n/exemption for product? m FDA.	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	iginal product rect from mfr? se manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.14 undle/ 3.11	Dimension Depth 1.84	pos (US msm Width 1.84	Each Gram Milliliter	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION	Dimensic Depth 1.84	bns (US msn Width 1.84 8.3	Each Gram Milliliter No. Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BowCarton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION	Dimensic Depth 1.84	pos (US msm Width 1.84	Each Gram Milliliter Notes.) Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BowCarton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	Item/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION	Dimensic Depth 1.84	IFORMATION Ons (US msm Width 1.84 8.3 Vendor #: Whsl. Code	Each Gram Milliliter Notes.) Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BowCarton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION (WAC) (\$)	Dimensic Depth 1.84	IFORMATION Ons (US msm Width 1.84 8.3 Vendor #: Whsl. Code	Each Gram Milliliter Notes.) Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each Bow/Carton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased direction of the source	ginal product rect from mfr? the manufacturer f		kaged product	Item/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION (WAC) (\$)	Dimensic Depth 1.84	IFORMATION Ons (US msm Width 1.84 8.3 Vendor #: Whsl. Code	Each Gram Milliliter Notes.) Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		
Does supplier meet DSCSA defini 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/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each Bow/Carton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for product? m FDA. Saleable	GTIN Quantity	Yes No No Yes No AND HIBCC PRODUCT IN	NFORMATION	GLN: GCP: If yes, was or purchased dii Provide source GTIM 0033	ginal product ect from mfr? se manufacturer f I-14 I-1722950015	for repac	Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost As of date:	1 Vial) Weight Lbs. 0.14 undle/ 3.11 COST INFORMATION (WAC) (\$)	Dimensic Depth 1.84	IFORMATION Ons (US msm Width 1.84 8.3 Vendor #: Whsl. Code	Each Gram Milliliter Notes.) Height 3.23 3.8	Volume (Cube) 10.86	Pieces 1 24		



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard? d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:
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	Is the product a NIOSH hazardous drug? If yes, indicate which:
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA?	
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: Yes No https://opioidanalgesicrems.com/home.html
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Yes Prathima Arrabelly Phone: (631) 881-4614 Ext. 1412 DEA #: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments
Is the Product	Continents
Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. Yes Listed Chemical (List I or II) No If yes, indicate which: Schedule No. 2 Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS 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 Yes	contact - customerservice@camberpharma.com
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.
MISCELLANE	OUS NOTES and/or Image of Product Barcode:
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	nt 1301.72.



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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: 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:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?