

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Introduction Type: New Item										Final Version			Date:	4/19	9/2017
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name:	Camber Pharmaceuti		Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.									
Application Number for ND				207419	207419			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F							
DUNS:	82-667-4775							Other Temperature Range Requirement							
Proprietary Name (If Applical	ble) and Established	Name: Oxycodo	MG/325MG 100CT						ite in)					1	
Selling Unit NDC:	31722-950-01		Individual Unit NDC:	31722-950-01											•
UDI CVX Code:			MVX Code:			Is this product to be shipped to customers on ice?  No						_			
Description:	in on other	in other				Is this product to be shipped to customers on dry ice?  No									
												-			
Active Ingredient(s): Oxycodone and Acetaminophen								b. Contact for temperature excursion questions:							
UDI for Additional Product Information							Name: Number	Soma Raju 732-529-0423							
URL for Additional Product Information: www.camberpharma.com  Address: 1031 Centennial Avenue			Address 2:				Group E-mail: 732-329-0423 somaraju@heterousa.com				m				
City:	Piscataway			State:	NI	Zip:	108	8854	- Group L	-man.		30maraju@1	leterousa.com		
Key Contact:	Customer Service			Email:	customerservice@camberpharma.co				c. Special regulations for product in any states?				No		
Phone Number:	732-529-0430			Fax: 732-562-8788					Special returns requirements for this product?  No						-
Product Therapeutic Classific															-
d. Store product (unit of sale) upright? No															
ADDITIONA	AL PRODUCT INFORM	ATION		PRODUCT DESCRIPTION INFORMATION				Protect product (unit of sale) from light?						_	
Is the Product										e. Shelf life: 24 Month					Months
a legend device?		No		Size: 100				Initial sh	nelf life at launch (if o	different):				Months	
reverse numbered?		No		Size:											
co-licensed?	<u>No</u>			Strength:			7.5MG/325MG			ORDER INFORMATION					
Is the Product	Direct-Ship Only Unit of Use				_				Unit of S	Sala		What is the	NDC selling	unit?	
is the Floduct	the Product			Dosage Form:			tablet			Bottle		1 box of 24 b		unit.	
				_				х	Box/Carton			g. 1 Box of 1	0 Vials)		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			Product Shape: capsule					Ampule				*			
If Unit Dose NDC, indicate NI	DC here:			capsule				Glass Minimum order quantity? Yes					Yes		
			Product Color: White to Off White				Tube								
Country of Origin United States							Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under the Trade Agreements Act (TAA)?			Product Imprint: T 193'			Vial Powder Sql Each				type r					
							Vial Power Multi		24	Inner/Carton	n/Pack				
								'  <u> </u>	Other: Write In			Case	vi don		
			FOR GENERIC DRUG PRODUCT	S											
										B.114.B		/ / - / · · ·			
				Authorized Generic *If Authorized Generic, other section fields are not applicable				PHARMACY ORD							
I. Orange Book Rating: AB			neius are not applicable					Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?:  Percocet													Each Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									(Write-in, e.g. 1 Vial)				Milliliter		
			· · ·	,									,		
Does supplier meet DSCSA of			Yes	GLN:						ITEM AN	ND PACKING	INFORMATI	ON		
Is product exempt from DSC	SA?		No								D'				
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Depth	nsions (US m Height	nsmts.) Width	Volume (Cube)	# Pieces:
Is product repackaged?			No	If Yes, was origin	al product r	nurchased direct	1		Item:		Deptil			(Cube)	
Is product sold by manufactu	urer's exclusive distri		No	from mfr?	a. p. oaaot p		_			0.14		3.225	1.835		
Has FDA granted waiver/exce			No	If yes, attach doc	umentation	from FDA.			Box/Carton/Bundle/	3.11	12.3	3.8	8.3	0.225	24
									Inner Pack:	3.11	12.5	3.0	0.5	0.223	24
			GTIN PRODUCT INFORMATION						Case:						
			Saleable Level Unit	9		Overation	·	TINI 4.4	Pallet:			-		<del></del>	+
Serialized?	Yes	х	Item Offic	<b>X</b> 2D		Quantition 1		TIN-14 0331722950015	Pallet:						
If not, when?	103	1 x	Box/Carton/Bundle/Inner Pack X	x 2D		inear 24		0331722950012	UPC:	Case:					
Items aggregated?	aggregated?         No         Case         2D         Linear           Pallet         2D         Linear								Carton:						
	2D Linear							COST	WHOLESALER USE ONLY:						
				2D		inear			D			Vandar #.			
					2D Linear					Regular Cost Invoice Cost (WAC) (\$) \$15.11			Vendor #: Whsl. Code #:		
				J	2D Linear				Federal Excise Tax Pe		ψ10.11	Fineline Co			
-									As of date:			1			
			Attach copy of SAFETY DATA SHEE	ET (SDS) or non haz	ard letter, P/	ACKAGE INSERT	T, LABEL	AND PHOTO OF PRO	DUCT PACKAGING and B.	ARCODE.				-	
*Please provide any addition	al information on pag	۵2			See new	n 3 for Designa	ted Dror	Shin Only	Signatur	ro.					



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): **SDS Hazard Classification** a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No 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? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity **REMS Program Manager Name:** Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Small Quantity (49 CFR 173.4) Wholesale distributor support: No Special Permit; DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: No by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments Controlled Substance? Yes Controlled by State(s)? Yes Registry: ARCOS Reportable? Yes Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code CII- oxyodone 9143 Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No URL/Link to returns policy: contact - customerservice@camberpharma.com Restricted to retail pharmacy only: Yes Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



## **Standard Pharmaceutical Product Information (Page 3)**

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 Yes	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern							
b. Autofax         No         Fax Number:           c. Fax         Yes         Fax Number:         732-562-8788           d. Phone only         No         Phone No.:	Shipping lead time of PO: 24/48 Hours Days							
e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:	Ships same day for next day receipt:  Ships for second day receipt:  No Ships regular ground for 3-10 days receipt:  Yes							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order: No	Overnight receipt available: Yes							
Drop Ship service fee billed with each order:  No	PO Receipt cut off time: 2:30PM Eastern							
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:   x X Tuesday Wednesday Thursday Friday							
	Priority Overnight receipt available: Yes							
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST							
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:         No           PO Receipt Cut off time:           Phone:         Yes         Phone #:         Fax #:         732-562-8788           Overnight Fees apply:         Yes         Yes         No							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	Contact # if product is received damaged:  Is product returnable for credit:  Ves  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?  No							