



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

Version 2024

Introduction Type: New Item☒ Final VersionDate: 2/25/2026**PRODUCT INFORMATION**

Company Name:	Camber Pharmaceuticals, Inc.	Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	207419	NDA 505(b) Type:	NOT APPLICABLE
Medical Device Class, if applicable:			
DUNS:	11-856-3719		
Proprietary Name (If Applicable) and Established Name:	Oxycodone and Acetaminophen Tablets, USP 7.5 mg/325 mg		
Selling Unit NDC:	31722-950-05	Unit of Use NDC:	331722950053
UDI		CVX Code:	
		MVX Code:	
Description:	Oxycodone and Acetaminophen Tablets, USP 7.5 mg/325 mg		
Active Ingredient(s):	Oxycodone hydrochloride, USP, acetaminophen, USP		
URL for Additional Product Information:	www.camberpharma.com		
Address:	800 Centennial Ave, Suite 1	Address 2:	
City:	Piscataway	State:	NJ
Key Contact:	Customer Service	Zip:	08854
Phone Number:	1-866-827-3647	Email:	customerservice@camberpharma.com
		Fax:	732-562-8788
Product Therapeutic Classification:	Combination full opioid agonist, and non-opioid, non-salicylate analgesic and antipyretic		

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:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	*Yes
	*Yes
d. Store product (unit of sale) upright?	
	No
e. Shelf life:	
Protect product (unit of sale) from light?	No
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT 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	Dye, Corn, Alcohol, Animal	
preservative-free?	Yes		
correctional institution block?	No	Country of Origin	USA
opioid?	Yes		
Cannabinoid?	No	Is this product covered under the Trade Agreements Act (TAA)?	Yes
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	500 ct
Strength:	7.5 mg/325 mg
Dosage Form:	Tablet
Product Shape:	Capsule
Product Color:	White to off-white
Product Imprint:	Debossed with 'T 193' on one side and plain on other side

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:	AA	☐ Authorized Generic	*If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Percocet		

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0843368117603
Is product exempt from DSCSA?	No	GCP:	
If yes, select exemption:		If yes, was original product purchased direct from mfr?	
Other exemption - Write in:		Provide source manufacturer for repackaged product	
Is product repackaged?	No		
Is product sold by manufacturer's exclusive distributor?	Yes		
Has FDA granted waiver/exception/exemption for product?	No		
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
☒ Item/Each	N	1		00331722950053	
☐ Box/ Carton/ Bundle/ Inner Pack					
☒ Case	N	12		10331722950050	
☐ Pallet					

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?	
☒ Bottle		1 Bottle of 500 Tablets	
☐ Box/ Carton		(Write-in, e.g. 1 Box of 10 Vials)	
☐ Ampule			
☐ Glass		Minimum order quantity?	Yes
☐ Tube			
☐ Vial Liquid Sgl		If Yes, how many of which package type?	
☐ Vial Liquid Multi		12 Each	
☐ Vial Powder Sgl		Inner/ Carton/ Pack	
☐ Vial Powder Multi		Case	
☐ Other: Write In			

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?		Rx billing unit to pharmacy:	
(Write-in, e.g. 1 Vial)		Each	
HCP/CS J-Code:		Gram	
		Milliliter	

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.58	3.1	3.1	5.56	53.43	1
Case:	7.4	13	9.8	6.5	828.1	12
Pallet:						

COST INFORMATION

Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$75.55	Whsl. Code #:	
As of date:	3/14/2019	Fineline Code:	

WHOLESALE USE ONLY:

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?	☐ No		
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?	☐		
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?	☐		
Is the product restricted for air shipment? If so, indicate restriction:		☐ No	
☐ 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?	☐ Yes	Controlled Substance Code	9143
Controlled by State(s)?	☐ Yes	Listed Chemical (List I or II)	☐ No
ARCOS Reportable?	☐ Yes	If yes, indicate which:	
Schedule No.	2	Is it a scheduled listed chemical product?:	☐ No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		☐ Yes	
Restricted to retail pharmacy only:		☐ No	
Restricted to hospital, clinics, and physician offices only:		☐ No	
Restricted from US territories? (explain in comments)		☐ No	
Comments:			
SDS Hazard Classification			
☒ Organic	☐ Corrosive		
☐ Inorganic	☐ Oxidizer		
☐ Steroid/Androgen	☐ Contact Hazard		
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		☐ No	
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?		☐ Yes	
If Yes, is it managed with a pharmacy registry?		☐ No	
Website URL:		www.OpioidAnalgesicREMS.com	
Med Guide Required		☐ Yes	
Limited Distribution Requirement		☐ No	
Comments / Details: (For example, iPledge program?)		Opioid Analgesic REMS Shared System REMS Program	
REMS:		☐ Yes	
REMS Program Manager Name:		Syneos Health	Phone: 800-503-0784
Supplier Manages REMS registry exclusively:		☐ No	
Wholesale distributor support:		☐ No	
Provider Name:			DEA #:
Site Enrollment Number assigned by Supplier:			NCPDP#:
			NPI #:
Comments			
Registry:		☐ No	
Registry Program Contact Name:			Phone:
Comments			
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		☐ Yes	
URL/Link to returns policy:		contact - customerservice@camberpharma.com	
Special regulations or returns requirements for this product in certain states? ☐ Yes			
If so, which states? Other requirements? Comments:			
DEA Form 222 or its electronic equivalent is required for all returns in all states.			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.			

Release DATE



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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
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: Fax Number: Fax Number: Phone No.: Site Address:	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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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?