

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduct	tion Type:	New Item		Final Version			Date:	1/25	/2019	
			PRODUCT INFORMAT	ION						SPECIAL HANDLI	ING AND STO	RAGE REQ	UIREMENTS	*		
Company Name:	Camber Pharmaceuticals Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for ND	A/ANDA/BLA (drug);	2114	11487			Temper	Temperature Range Co				Controlled Room – between 20 and 25 C (68° – 77° f					
DUNS:	82-667-4775				1			Other Te	Other Temperature Range Requirement							
	icable) and Established Name: Hydrocodone APAP 7.5mg/325mg- 500ct				UDO 10 04700F 44			(w	rite in)							
Selling Unit NDC:	Unit NDC: 31722-942-05				UPC: 3.31723E+11 MVX Code: 3.31723E+11			la di la di	and and the base of the second t		- 10		No			
							<u></u>					-				
Description:	Is this product to be shipped to customers on dry ice?															
Active Ingredient(s): Hydrocodone APAP								b. Contact for tempera	Down But							
URL for Additional Product Information: www.camberpharma.com								Name: Number:			Soma Raju 732-529-0423					
Address:					Address 2:			Group I	somaraju@heterousa.com							
City:	Piscataway				State: NJ Zip: 08854 Email: customerservice@camberpharma.com											
Key Contact:	Customer Service							c. Special regulations	No No							
Phone Number:	732-529-0430				Fax: 732-562-8788			Special returns requirements for this product? No					=			
Product Therapeutic Classification:										at Olean and that for the feed of a lead and the fee						
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION			d. Store product (unit of sale) upright? Protect product (unit of sale) from light? No					_		
Is the Product				110230122331111311111101111111111				e. Shelf life:				Months				
a legend device?				١.	0	500				helf life at launch (if	different):			24	Months	
reverse numbered?		No		`	Size: 500											
co-licensed?	No			Strength: 7.5mg/325mg			ORDER INFORMATION									
Is the Product Is the Product	Direct-Ship Only			_				Unit of	Pala		What is the	NDC selling	unit?			
is the Froduct	ne Product Unit of Use		1	Dosage Form:	Oral	Solid Tablet		III on the state of the state o	Bottle		1 case of 12		uiii.			
If Unit Dose, is item bar coded to unit dose for hospital scanning?							x	Box/Carton			.g. 1 Box of 1	0 Vials)				
		ital scalling:			Product Shape: Capsule				Ampule							
If Unit Dose NDC, indicate NDC here:									Glass Tube		Minimum o	rder quantity	/?	Yes		
Country of Origin		India		ı	Product Color: Off White				Vial Liquid Sgl							
					Product Imprint: T 258'				Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under the Trade Agreements Act (TAA)?				'	1 200			Vial Powder Sql Each								
								J	Vial Power Multi Other: Write In		12	Inner/Carton Case	/Pack			
FOR GENERIC DRUG PRODUCTS										Other: write in			Case			
Authorized Generic *If Authorized Generic, other section							PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating:				fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Norco							(Write-in, e.g. 1 Vial)			Each Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													Milliliter			
				, ,								l				
Does supplier meet DSCSA		urer?	Yes	GLN	l:					ITEM A	ND PACKING	INFORMAT	ION			
Is product exempt from DSC If yes, select exemption:	SCSA? No										Dimor	nsions (US n	nemte \	Volume		
Other exemption - Write in:										Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?			No	If Ye	s, was original	product pure	chased direct		Item:	0.573		5.22	2.895			
Is product sold by manufactor			No		n mfr?					0.575		5.22	2.033			
Has FDA granted waiver/exc	eption/exemption for	product?	No	If ye	s, attach docun	mentation from	m FDA.		Box/Carton/Bundle/ Inner Pack:							
			GTIN PRODUCT INFORM	ATION					Case:							
				aleable					Just.	7.5	12.1	5.5	9	0.34	12	
			Level	Unit			Quantity	GTIN-14	Pallet:						84	
Serialized?	Yes	х	Item		X 2D	Linear		00331722942058								
If not, when? Items aggregated?	No	x	Box/Carton/Bundle/Inner Pack	х	X 2D 2D	Linear		10331722942055	UPC:	Case: Carton:						
items aggregated:	ed? No Case 2D Linear 2D L															
	2D Linear						COST	WHOLESALER USE ONLY:								
					2D	Linear	r									
				 -	2D 2D	Linear Linear			Regular Cost Invoice Cost (WAC) (\$) \$80.00				Vendor #: Whsl. Code #:			
		<u> </u>				Lilidai		ļ.	Federal Excise Tax Pe		ψου.00	Fineline Co				
									As of date:							
l			Attach copy of SAFETY DATA	A SHEET (SD												
*Please provide any addition	nai information on pag	e 2.				See new p. 3	for Designated	Drop Ship Only.	Signatu	re:						



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? Yes Cargo If Yes, is it managed with a pharmacy registry? No Website URL: Passenger & Cargo N/A Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο None 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 None 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 9193 RETURN INSTRUCTIONS Listed Chemical (List I or II) No 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						