

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

Version 2021						Introduction ¹	Туре:	New Item		x Final Version			Date:	6/23	/2024			
			PRODUCT INFORMAT	ION						SPECIAL HAND	LING AND STO	RAGE REQUI	REMENTS*					
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 211487 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																		
Medical Device Class, if applical		. , ,	<u> </u>						1									
DUNS:	11-856-3719								1	Other Temperature Range R	equirement							
Proprietary Name (If Applicable) a	and Established Na	me: Hydro	ocodone Bitartrate and Acetar	ninophen Tablet	s, USP 7.5 mg	/325 mg			1	(write in)								
Selling Unit NDC:	31722-942-01		Unit of Use NDC:			UPC:	3317229	942010		Notes								
UDI			CVX Code:			MVX Code:												
Description:	Hydrocodone Bitar	trate and Acetamin	nophen Tablets, USP 7.5 mg/3	25 mg					1	Is this product to be shipped	to customers on	ice?		No]			
•				ŭ						Is this product to be shipped	to customers on	dry ice?		No				
Active Ingredient(s):		Hydrocodone bitar	rtrate, USP, acetaminophen, l	JSP					1						•			
b. Contact for temperature excursion questions:																		
	RL for Additional Product Information: www.camberpharma.com			Address O			Name: Soma Raju											
Address:		Centennial Ave, Suite 1			Address 2:		Number: 732-529-04											
City:	Piscataway		State:			NJ	Zip:		-	Group E-mail:		somaraju@	heterousa.co	<u>m</u>				
Key Contact:	Customer Service 1-866-827-3647		Email:			customerservice@camberpharma.com 732-562-8788			- Cunnint room	ulatiana fau mua durat in anu.	-1-12			*Yes	1			
Phone Number: Product Therapeutic Classificatio		Combination anioid and	d non-opioid, non-salicylate analgesic ar	ad antinuratio	гах.	132-302-0100	132-562-8188			lations for product in any		,						
Product Therapeutic Classificatio	on:	Combination opioid, and	non-opioid, non-salicylate analgesic ar	id antipyretic						Special returns requirements	s for this product			*Yes				
	ADDITIO	NAL PRODUCT II	NEORMATION			PRODUCT	DESCRIP	TION INFORMATION	d Store produ	ct (unit of sale) upright?				No	1			
T	ADDITIO	MALTRODUCT		Discret Ohio O	ali.	TRODUCT	DECOR	TION IN CHIMATION	u. Store prout	· · · · -]			
The product is? a legend device?		N.	Is the Product	Direct-Ship C Neither	niy		4	100 ct	e. Shelf life:	Protect product (unit of sa	le) from light?			No 24	Months			
if yes, enter class #		No	Is the Product Orphan Drug Status	Neitriei		Size:	'	100 Ct	e. Shell life:	Initial shelf life at launch (i	f different):			24	Months			
a product kit?		No	Orphan Drug Status				7	7.5 mg/325 mg		ililiai Sileli ille at laulicii (i	i dillerentj.				WIOTILIS			
if yes, list NDCs of		140	FDA Approval Status			Strength:	'	.o mg/020 mg			ORDER INFOR	MATION						
component parts						B	Т	Tablet										
reverse numbered?		No				Dosage For	m:			Unit of Sale		What is the	NDC selling	unit?				
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 1	00 Tablets					
latex-free?					Product Sha	ane.	Capsule	Box/Carton				(Write-in, e.g. 1 Box of 10 Vials)						
preservative-free?		Yes		., _, _						Ampule								
correctional institution block?		No				Product Col	lor:	Off white/white		Glass		Minimum o	rder quantit	y?	Yes			
opioid?		Yes	0	1104			_	Debossed 'T 258' on one side and		Tube								
Cannabinoid?		No	Country of Origin	USA		Product Imp	print: pl	lain on other side with bisect line		Vial Liquid Sgl		If Van hau		iah maakama	4			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered u	ndor the						Vial Liquid Multi				ich package	type?			
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		Yes	ļ							Inner/Cartor	/Pack				
ii onii bose, indicate Nbo nere.			Trade rigidements rick (103					Other: Write In			Case	in don				
			FOR GENERIC DRUG PRO	DDUCTS														
					Aut	thorized Generic	*If Autho	orized Generic, other		PH <i>A</i>	RMACY ORDER	R / BILL UNIT						
I. Orange Book Rating:	AA					section fields are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Norco									Each									
-									(Write-in, e.g.	1 Vial)			Gram					
		DRUG SUPPI	LY CHAIN SECURITY ACT (I	OSCSA) INFOR	MATION								Milliliter					
				_														
Does supplier meet DSCSA defini		rer?	Yes No	_	GLN:	0860000397957				ITEM .	AND PACKING I	NFORMATIO	N					
Is product exempt from DSCSA?			UVU						-									
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msr	•	Volume	Saleable #			
Other exemption - Write in:			NI-		.,						Depth	Width	Height	(Cube)	Pieces			
Is product repackaged?		10	No			iginal product			Item/Each:	0.14	1.84	1.84	3.23	10.86	1			
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	-		rect from mfr? ce manufacturer f	for renoct	kaged product	Box/Carton/Bi	ındle/								
If yes, attach documentation fro		oduct?	140		Frovide Sour	Le manuracturer i	ioi repaci	kageu product	Inner Pack:	mule/								
yoo, anaon aooamonanon no									Case:									
				IFORMATION					1	3.8	12.3	8.3	3.8	387.94	24			
		GTI	IN AND HIBCC PRODUCT IN						Pallet:									
		GTI	IN AND HIBCC PRODUCT IN															
Saleable Unit of Measure	Sa	GTI aleable Quantity	IN AND HIBCC PRODUCT IN		GTI		_	Unit of Use GTIN-14										
X Item/Each	Sa					N-14 31722942010		Unit of Use GTIN-14										
X Item/Each Box/Carton/Bundle/Inner Pack	Sá	aleable Quantity			0033	31722942010		Unit of Use GTIN-14		COST INFORMATION			WHOLESAL	ER USE ONL	-Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sá	aleable Quantity			0033			Unit of Use GTIN-14		COST INFORMATION			WHOLESAL	ER USE ONL	-Y:			
X Item/Each Box/Carton/Bundle/Inner Pack	Sa	aleable Quantity			0033	31722942010		Unit of Use GTIN-14	Regular Cost		A.s	Vendor #:		ER USE ONL	-Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	S:	aleable Quantity			0033	31722942010		Unit of Use GTIN-14	Regular Cost Invoice Cost (\$16.00	Vendor #: Whsl. Code	· #:	ER USE ONL	-Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Si	aleable Quantity			0033	31722942010		Unit of Use GTIN-14	Invoice Cost (WAC) (\$)	\$16.00	Vendor #:	· #:	ER USE ONL	.Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Si	aleable Quantity			0033	31722942010		Unit of Use GTIN-14			\$16.00	Vendor #: Whsl. Code	· #:	ER USE ONL	Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	aleable Quantity			0033	31722942010		Unit of Use GTIN-14	Invoice Cost (WAC) (\$)	\$16.00	Vendor #: Whsl. Code	· #:	ER USE ONL	Y:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	Sa	aleable Quantity		TA SHEET (SDS	1033	31722942010 31722942017			Invoice Cost (As of date:	WAC) (\$) 7/1/2020	\$16.00	Vendor #: Whsl. Code	· #:	ER USE ONL	Y:			



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No 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 Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard? d. Does this product require special clean-up instructions? (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)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number 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:
Is the Product	Comments
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: 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.
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR I	Part 1301.72.



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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 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?