

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

Version 2024						Introduction T	ype: New Iten	n		x Final Version			Date:	5/17/	2025
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Applicat	ion: ANDA		a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/510	(k):	211487			NDA 505(b) Type:	NOT APPLICABL	_E		emperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719								[ ]	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ime:	Hydrocodone Bitartrate and Acetar		ets, USP 5 mg/3					(write in)					
Selling Unit NDC:	31722-996-05		Unit of Use NDC:			UPC:	331722996051		N	lotes					
UDI			CVX Code:			MVX Code:			1						
Description:	Hydrocodone Bita	rtrate and Ace	taminophen Tablets, USP 5 mg/32	5 mg					T Is	this product to be shipped	d to customers on i	ce?		No	
									l:	this product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s):		Hydrocodone	e bitartrate, USP, acetaminophen, l	JSP							41				
URL for Additional Product Inforn		www.camber	nharma oom							emperature excursion que lame:	estions:	Soma Raju			
Address:	800 Centennial Av		рпанна.сон			Address 2:			a l	lumber:		732-529-042	23		
City:	Piscataway	o, callo i			State:	NJ	Zip: 08854			Froup E-mail:			heterousa.cor	n	
Key Contact:	Customer Service	!			Email:	customerservice(	Ocamberpharma.com		Group E-main.				_		
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regul	ations for product in any	states?			*Yes	
Product Therapeutic Classificatio	n:	Combination opioi	id, and non-opioid, non-salicylate analgesic and	l antipyretic					S	pecial returns requirement	s for this product?			*Yes	
_					_										
	ADDITIO	ONAL PRODU	ICT INFORMATION			PRODUCT [	DESCRIPTION INFORMA	TION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only					rotect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither	-	Size:	500 ct		e. Shelf life:	. ,	, ,			24	Months
if yes, enter class #			Orphan Drug Status			Size.			l l	nitial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	5 mg/325 mg								
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	MATION			
component parts reverse numbered?		ls.				Dosage Forn	n: Tablet		II .	1-16 -60-1-		Minat in the	NDC selling		
co-licensed?		No	Allergens Present						ll -	Init of Sale  x Bottle		1 Bottle of 5		unit?	
latex-free?		No Yes					Capsule		ll –	Box/Carton			g. 1 Box of 1	0 Viale)	
preservative-free?		Yes	Corr	n, Dye		Product Sha	pe:			Ampule		(**************************************	.g. 1 Dox 01 1	o viais)	
correctional institution block?		No				Burnet Out	Off white/white			Glass		Minimum o	rder quantity	1?	Yes
opioid?		Yes				Product Cold	or:			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impi	Debossed 'T 257' on one s			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					Froductimp	plain on other side with bis	sect line		Vial Liquid Multi				ich package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)?	Yes					Vial Powder Multi			Inner/Carton	n/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					A	thorized Generic	*If Authorized Generic, of	ther		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA			_			section fields are not app		Rec. sell unit to				nit to pharm	2011	
II. Generic Equivalent to What Bra		Norco							ixec. sen unit to	customer:	1	KX billing u	Each	acy.	
II. Generic Equivalent to What Brand?.							(Write-in, e.g. 1 Vial)								
		DRUG S	SUPPLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Code				Milliliter		
													-		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0843368117603				ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msr		Volume	Saleable #
Other exemption - Write in:									1		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	avaluabe des	100	No Yes	_		riginal product pure	chased		Item/Each:	0.57	2.90	2.90	5.22	43.75	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	-	direct from m		r repackaged product		Box/Carton/Bur	idlo/					
If yes, attach documentation from		oductr	140		Flovide Soul	ce manufacturer to	r repackageu product		Inner Pack:	lule/					
,									Case:		10.1			500.05	
			GTIN AND HIBCC PRODUCT I	NFORMATION						7.5	12.1	9	5.5	598.95	12
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN	N-14							
		Quantity													
x Item/Each	N	1			003	31722996051			l <u> </u>	COST INFORMATION			WHOLESAL	ER USE ONL	٧.
Box/Carton/Bundle/Inner Pack  X Case	N	12			102	31722996058	-			COST INFORMATION			WHOLESAL	EK USE UNL	1.
X Case Pallet	IN	12			103	01122990000	-		Regular Cost			Vendor #:			
, and									Invoice Cost (W	AC) (\$)	\$60.00	Whsl. Code	#:		
							1				\$55.00	Fineline Co			
							]		As of date:	12/10/2020					
									11						
11									11			1			
*Please provide any additional inf		•	Attach copy of SAFETY DA	ATA SHEET (SI	OS) or non haza		INSERT, LABEL AND PH		PRODUCT PACKAG	ING and BARCODE.					



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

#### Version 2024

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	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GIASSIIIVARION						
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
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?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number							
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	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	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL: <a href="https://opioidanalgesicrems.com/home.html">https://opioidanalgesicrems.com/home.html</a>						
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required Yes						
Passenger	Limited Distribution Requirement No						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: Yes						
RQ Threshold:	REMS Program Manager Name: Murali Kuraku Phone: 631-851-0550 Ext. 1433						
Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit?	Supplier Manages REMS registry exclusively:  Wholesale distributor support:						
No (if yes, identify method below)	writesate distributed support.  Provider Name:  DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments Arpitha Teegala is included as an additional responsible person for Opioid REMS administration.						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? Yes Controlled Substance Code 9193	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes Listed Chemical (List I or II) No							
ARCOS Reportable? Yes If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. 2 Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	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:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:  No	product in certain states?  Yes						
Restricted from US territories? (explain in comments)  No	If so, which states? Other requirements? Comments?						
Comments:	DEA Form 222 or its electronic equivalent is required for all returns in all states.						
Commente.	DEAT 1 OTH EZZ OF ItS GROUND EQUIVAIENT S rEQUIRED FOR AN INTEREST.						
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 Pa	rt 1301.72.						



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

#### Version 2024

### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Purchase order ally receipt cut off time by supplier  a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing					
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No.  Expedited freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:					
d. Phone only e. Suppler Web Site only Site Address:  Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days								
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days					
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