

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

Version 2021					Introduction	Туре:	New Item		x Final Versior			Date:	11/15	/2023
		PRODUCT INFORM	ATION						SPECIAL	HANDLING 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/ANI	DA/BLA (drug); PMA/510(k)(n	ned device):	216800						Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:													
DUNS:	11-856-3719								Other Temperature Ra	nge Requirement				
Proprietary Name (If Applicable) a		Bupropion Hydrochloride Extende		SP (SR) 15					(write in)					
Selling Unit NDC:	31722-067-05	Unit of Use NDC	:		UPC:	33172206	7058		Notes					
UDI		CVX Code:			MVX Code:									
Description:	Bupropion Hydrochloride Exte	nded-Release Tablets, USP (SR) 15	50 mg						Is this product to be sh				No	
Active Ingredient(s): Bupropion Hydrochloride Is this product to be shipped to customers on dry ice? No														
Active Ingredient(s): Bupropion Hydrochioride b. Contact for temperature excursion questions:														
URL for Additional Product Inform	ation: www.camb	erpharma.com							Name:	rquestions.	Soma Raju			
Address:	1031 Centennial Ave (and) 80	0 Centennial Ave, Suite 1			Address 2:				Number:		732-529-042	23		
City:	Piscataway					Zip: 0	8854	Group E-mail: somaraju@heterousa.com					<u>n</u>	
Key Contact:	Customer Service			Email:	customerservice	@camberph	harma.com							
Phone Number:	1-866-827-3647			Fax:	732-562-8788				ulations for product in	-			No	
Product Therapeutic Classification	n: Aminoketo	ne Antidepressant (NDRI)							Special returns require	ments for this product?	2		No	
		DUCT INFORMATION			PRODUCT	DESCRIPT		d Change are de		12			Ne	
	ADDITIONAL PRO		Discut Citil O (		PRODUCT	DESCRIPT	ION INFORMATION	a. Store produ	Ict (unit of sale) uprig				No	
The product is?		Is the Product	Direct-Ship Only Neither		1		0		Protect product (unit	of sale) from light?			No	
a legend device? if yes, enter class #	No	Is the Product Orphan Drug Status	Neither		Size:	50	0 ct	e. Shelf life:	Initial shelf life at lau	ob (if difforent)			24	Months Months
a product kit?	No	Orphan Drug Status				15	0 mg		Initial shelf life at lau	ich (ir amerent):				wonths
if yes, list NDCs of	110	FDA Approval Status			Strength:	10	onig			ORDER INFOR	MATION			
component parts		· · · · · · · · · · · · · · · · · · ·			D	Fili	m coated 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 5	00 Tablets		
latex-free?	Yes		Dye		Product Sha		und, biconvex, bevel		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	Yes		-,-			ed	ged		Ampule				- 1	
correctional institution block?	No				Product Col	lor: Gr	een		Glass		Minimum o	rder quantity	?	Yes
opioid? Cannabinoid?	No	Country of Origin	India				1 49' on one side and		Tube Vial Liquid S					
If Unit Dose, is item bar coded to u		Country of Origin	inuia		Product Imp		in on other side		Vial Liquid M		If Yes how	many of whi	ch package t	vne?
hospital scanning?		Is this product covered	under the			1.0			Vial Powder			Each	on puonago i	<b>,</b> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:		Trade Agreements Act	(TAA)? No						Vial Power N	ulti		Inner/Carton	/Pack	
									Other: Write	n		Case		
		FOR GENERIC DRUG PI	RODUCTS											
				Au	thorized Generic		ized Generic, other elds are not applicable	-	-	PHARMACY ORDE				
	AB1	200				Section ne	nus are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Brand?: Wellbutrin® SR							(Write-in, e.g. 1 Vial) Gram							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION														
											L	1		
Does supplier meet DSCSA definit	tion of manufacturer?	Yes	GLN	4:	0331722000000					TEM AND PACKING	INFORMATIO	N		
Is product exempt from DSCSA?		No												
If yes, select exemption:			GCP	•:					Weight Lt	Dimens	sions (US msn	nts.)	· · · · · · · · · · · · · · · · · · ·	Saleable #
Other exemption - Write in:						_			weight Li	s. Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No			riginal product pu	rchased		Item/Each:	0.74	3.375	3.375	6	68.34	1
Is product sold by manufacturer's Has FDA granted waiver/exceptior		Yes		ct from m	ce manufacturer f	or ronookor	and product	Box/Carton/B	undlo/		_			
If yes, attach documentation from		No	1100	vide sour	ce manufacturer is	orrepackag		Inner Pack:						
								Case:	10	44.5	44.05	8	1 205 00	12
		GTIN AND HIBCC PRODUCT	INFORMATION						10	14.5	11.25	8	1,305.00	12
								Pallet:						
Saleable Unit of Measure	Saleable Qua	antity HIBCC			N-14	U	Init of Use GTIN-14							
X Item/Each	1			003	31722067058				COST INFORMAT	ON			ER USE ONL	v
Box/Carton/Bundle/Inner Pack	12	_		303	31722067059	-			COST INFORMAT	ON		WHOLESAL	ER USE ONL	r:
Pallet	12			303	01122001033	-		Regular Cost			Vendor #:			
		_				-		Invoice Cost (	WAC) (\$)	\$115.00	Whsl. Code	#:		
											Fineline Co			
								As of date:	10/16/2023					
μ														
*Place		Attach copy of SAFETY D	ATA SHEET (SDS) or	non haza			ABEL AND PHOTO OF P							
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:														

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

Version 2021 For Design	ated 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? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? (If yes, answer a-e below and provide SDS)	x       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:       Image: Contact Hazard         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       No
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? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
(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?	No       If Yes, is it managed with a pharmacy registry?       Website URL:
Is the product restricted for air shipment? If so, indicate restriction:          No         Passenger         Cargo         Passenger & Cargo         Is this a reportable quantity?	Med Guide Required     No       Limited Distribution Requirement     Image: Comments / Details: (For example, iPledge program?)       REMS:     No
RQ Threshold:       No         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	REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Image: Comments       Wholesale distributor support:     Image: Comments
Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? Schedule No. CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS       Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     Yes       URL/Link to returns policy:     Yes
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:     Ves	contact - customerservice@camberpharma.com         Special regulations or returns requirements for this product in certain states?         If so, which states? Other requirements? Comments?
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:



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

Version 2021 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:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available:       Image: Comparison of the co
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:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?