



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

Version 2021

Introduction Type: New Item

Final Version

Date: 9/12/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*				
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.		Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>		
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="214419"/>				Other Temperature Range Requirement (write in): <input type="text"/>		Notes: <input type="text"/>		
Medical Device Class, if applicable: <input type="text"/>				Is this product to be shipped to customers on ice? <input type="checkbox"/> No		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No		
DUNS: <input type="text" value="11-856-3719"/>				b. Contact for temperature excursion questions:		Name: <input type="text" value="Soma Raju"/>		
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Venlafaxine Extended-Release Tablets 225 mg"/>		Unit of Use NDC: <input type="text" value="31722-126-30"/>		Number: <input type="text" value="732-529-0423"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>		
Selling Unit NDC: <input type="text" value="31722-126-30"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>		c. Special regulations for product in any states? <input type="checkbox"/> No		
Description: <input type="text" value="Venlafaxine Extended-Release Tablets 225 mg"/>		Active Ingredient(s): <input type="text" value="Venlafaxine Hydrochloride, USP"/>		Special returns requirements for this product? <input type="checkbox"/> No		d. Store product (unit of sale) upright? <input type="checkbox"/> No		
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>		Address: <input type="text" value="1031 Centennial Ave (and) 800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Protect product (unit of sale) from light? <input type="checkbox"/> No		
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>		e. Shelf life: <input type="text" value="24"/> Months		
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>		Initial shelf life at launch (if different): <input type="text"/>		Months		
Phone Number: <input type="text" value="1-866-827-3647"/>		Fax: <input type="text" value="732-562-8788"/>						
Product Therapeutic Classification: <input type="text" value="Selective Serotonin and Norepinephrine Reuptake Inhibitor"/>								
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION				
The product is? <input type="checkbox"/> No	Is the Product... <input type="checkbox"/> Direct-Ship Only	Size: <input type="text" value="30 ct"/>					Unit of Sale: <input checked="" type="checkbox"/> Bottle	
if yes, enter class # <input type="text"/>	Is the Product... <input type="checkbox"/> Unit of Use	Strength: <input type="text" value="225 mg"/>					What is the NDC selling unit? <input type="text" value="1 Bottle of 30 Tablets"/>	
if yes, list NDCs of product kit <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="Film-coated tablet"/>					(Write-in, e.g. 1 Box of 10 Vials)	
if yes, list NDCs of component parts <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Round, biconvex"/>					Minimum order quantity? <input type="checkbox"/> Yes	
reverse numbered? <input type="checkbox"/> No	Allergens Present <input type="text" value="Corn, Alcohol, Wheat"/>	Product Color: <input type="text" value="White to off white"/>					If Yes, how many of which package type? <input type="text" value="24"/> Each	
co-licensed? <input type="checkbox"/> No	Country of Origin: <input type="text" value="USA"/>	Product Imprint: <input type="text" value="'395' on one side and blank on the other side"/>					Inner/ Carton/ Pack <input type="text"/>	
latex-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes					Case <input type="text"/>		
preservative-free? <input type="checkbox"/> Yes								
correctional institution block? <input type="checkbox"/> No								
opioid? <input type="checkbox"/> No								
Cannabinoid? <input type="checkbox"/> No								
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>								
If Unit Dose, indicate NDC here: <input type="text"/>								
FOR GENERIC DRUG PRODUCTS								
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable				
II. Generic Equivalent to What Brand?: <input type="text" value="Venlafaxine Hydrochloride Tablets"/>								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="0031722000000"/>						
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>						
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>						
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>						
Is product repackaged? <input type="checkbox"/> No								
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes								
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No								
If yes, attach documentation from FDA. <input type="text"/>								
GTIN AND HIBCC PRODUCT INFORMATION								
Saleable Unit of Measure: <input checked="" type="checkbox"/> Item/Each	Saleable Quantity: <input type="text" value="1"/>	HIBCC: <input type="text"/>	GTIN-14: <input type="text" value="00331722126304"/>	Unit of Use GTIN-14: <input type="text" value="00331722126304"/>				
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="10331722126301"/>	<input type="text"/>				
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				
ITEM AND PACKING INFORMATION				COST INFORMATION				
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces		
	Depth	Width	Height					
Item/Each:	0.12	1.75	1.75	3.5	10.72	1		
Box/ Carton/ Bundle/ Inner Pack:								
Case:	3.15	11	7.5	4	330.00	24		
Pallet:								
WHOLESALE USE ONLY:				COST INFORMATION				
Regular Cost <input type="text"/>	Invoice Cost (WAC) (\$) <input type="text" value="\$103.29"/>	Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>		Fineline Code: <input type="text"/>		
As of date: <input type="text" value="3/1/2023"/>								
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: <input type="text"/>				