



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

Version 2021

Introduction Type:

Final Version

Date:

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"/>		Medical Device Class, if applicable: <input type="text"/>		Other Temperature Range Requirement (write in): <input type="text"/>		Notes: <input type="text"/>	
DUNS: <input type="text" value="11-856-3719"/>		Proprietary Name (If Applicable) and Established Name: <input type="text" value="Venlafaxine Extended-Release Tablets 225 mg"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>	
Selling Unit NDC: <input type="text" value="31722-126-90"/>		Unit of Use NDC: <input type="text" value="31722-126-90"/>		UPC: <input type="text" value="331722126908"/>		b. Contact for temperature excursion questions:	
UDI: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>		Name: <input type="text" value="Soma Raju"/>	
Description: <input type="text" value="Venlafaxine Extended-Release Tablets 225 mg"/>		Active Ingredient(s): <input type="text" value="Venlafaxine Hydrochloride, USP"/>		Number: <input type="text" value="732-529-0423"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>	
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"/>		c. Special regulations for product in any states?	
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>		Special returns requirements for this product? <input type="text" value="No"/>	
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>		Fax: <input type="text" value="732-562-8788"/>		d. Store product (unit of sale) upright? <input type="text" value="No"/>	
Phone Number: <input type="text" value="1-866-827-3647"/>		Product Therapeutic Classification: <input type="text" value="Selective Serotonin and Norepinephrine Reuptake Inhibitor"/>				Protect product (unit of sale) from light? <input type="text" value="No"/>	
						e. Shelf life: <input type="text" value="24"/> Months	
						Initial shelf life at launch (if different): <input type="text"/>	
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? <input type="text" value="No"/>		Is the Product... <input type="text" value="Direct-Ship Only"/>		Size: <input type="text" value="90 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... <input type="text" value="Unit of Use"/>		Strength: <input type="text" value="225 mg"/>			
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"/>			
if yes, list NDCs of component parts <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Round, biconvex"/>			
reverse numbered? <input type="text" value="No"/>		Allergens Present <input type="text" value="Corn, Alcohol, Wheat"/>		Product Color: <input type="text" value="White to off white"/>			
co-licensed? <input type="text" value="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"/>			
latex-free? <input type="text" value="Yes"/>							
preservative-free? <input type="text" value="Yes"/>							
correctional institution block? <input type="text" value="No"/>							
opioid? <input type="text" value="No"/>							
Cannabinoid? <input type="text" value="No"/>							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>					
If Unit Dose, indicate NDC here: <input type="text"/>							
ORDER INFORMATION							
Unit of Sale				What is the NDC selling unit?			
<input checked="" type="checkbox"/>	Bottle			<input type="text" value="1 Bottle of 90 Tablets"/>			
<input type="checkbox"/>	Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)			
<input type="checkbox"/>	Ampule						
<input type="checkbox"/>	Glass			Minimum order quantity? <input type="text" value="Yes"/>			
<input type="checkbox"/>	Tube						
<input type="checkbox"/>	Vial Liquid Sgl						
<input type="checkbox"/>	Vial Liquid Multi			If Yes, how many of which package type?			
<input type="checkbox"/>	Vial Powder Sgl			<input type="text" value="24"/> Each			
<input type="checkbox"/>	Vial Power Multi			<input type="text"/>			
<input type="checkbox"/>	Other: Write In			Inner/Carton/Pack			
<input type="checkbox"/>				Case			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *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="text" value="Yes"/>		GLN: <input type="text" value="0031722000000"/>					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="text" value="No"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/>	Item/Each	<input type="text" value="1"/>				<input type="text" value="00331722126908"/>	
<input type="checkbox"/>	Box/Carton/Bundle/Inner Pack					<input type="text" value="00331722126905"/>	
<input checked="" type="checkbox"/>	Case	<input type="text" value="24"/>					
<input type="checkbox"/>	Pallet						
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
<input type="checkbox"/>							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		<input type="text" value="\$309.87"/>		Vendor #:		<input type="text"/>	
Invoice Cost (WAC) (\$)				Whsl. Code #:		<input type="text"/>	
As of date: <input type="text" value="3/1/2023"/>				Fineline Code:		<input type="text"/>	

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: