



# 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"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="214419"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Venlafaxine Extended-Release Tablets 75 mg"/>		Unit of Use NDC: <input type="text" value="31722-124-30"/>		UPC: <input type="text" value="331722124300"/>			
Selling Unit NDC: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
UDI: <input type="text"/>				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Description: <input type="text" value="Venlafaxine Extended-Release Tablets 75 mg"/>				Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
Active Ingredient(s): <input type="text" value="Venlafaxine Hydrochloride, USP"/>				<b>b. Contact for temperature excursion questions:</b>			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				Name: <input type="text" value="Soma Raju"/>			
Address: <input type="text" value="1031 Centennial Ave (and) 800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Number: <input type="text" value="732-529-0423"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
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 (SNRI)"/>				<b>c. Special regulations for product in any states?</b>			
				Special returns requirements for this product? <input type="checkbox"/> No			
				<b>d. Store product (unit of sale) upright?</b>			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				<b>e. Shelf life:</b>			
				Initial shelf life at launch (if different): <input type="text" value="24"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? <input type="checkbox"/> No		Is the Product... <input type="checkbox"/> Direct-Ship Only		Size: <input type="text" value="30 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... <input type="checkbox"/> Unit of Use		Strength: <input type="text" value="75 mg"/>			
if yes, list NDCs of product kit <input type="text"/>		Orphan Drug Status <input type="checkbox"/>		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="checkbox"/> No		Allergens Present <input type="text" value="Corn, Alcohol, Wheat"/>		Product Color: <input type="text" value="White to off white"/>			
co-licensed? <input type="checkbox"/> No		Country of Origin <input type="text" value="USA"/>		Product Imprint: <input type="text" value="'393' on one side and blank on the other side"/>			
latex-free? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes					
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"/>							
ORDER INFORMATION							
Unit of Sale <input checked="" type="checkbox"/> Bottle				What is the NDC selling unit? <input type="text" value="1 Bottle of 30 Tablets"/>			
<input type="checkbox"/> Box/Carton				(Write-in, e.g. 1 Box of 10 Vials)			
<input type="checkbox"/> Ampule				Minimum order quantity? <input type="checkbox"/> Yes			
<input type="checkbox"/> Glass							
<input type="checkbox"/> Tube				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Liquid Sgl				<input type="text" value="24"/> Each			
<input type="checkbox"/> Vial Liquid Multi				<input type="text"/>			
<input type="checkbox"/> Vial Powder Sgl				Inner/ Carton/ Pack			
<input type="checkbox"/> Vial Power Multi				Case			
<input type="checkbox"/> Other: Write In <input type="text"/>							
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="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"/>							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text"/>				Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)				<input type="checkbox"/> Each			
				<input type="checkbox"/> Gram			
				<input type="checkbox"/> Milliliter			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.08	1.75	1.75	3.5	7.875	1	
Box/Carton/Bundle/Inner Pack:							
Case:	2.55	11	7.5	4	304.5	24	
Pallet:							
GTIN AND HIBCC PRODUCT INFORMATION				COST 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="00331722124300"/>	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack						<input type="text" value="00331722124300"/>	
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>					<input type="text" value="10331722124307"/>	
<input type="checkbox"/> Pallet							
WHOLESALE USE ONLY:				COST INFORMATION			
Regular Cost		Invoice Cost (WAC) (\$)		Vendor #:			
		<input type="text" value="\$44.98"/>		<input type="text"/>			
As of date: <input type="text" value="3/1/2023"/>				Whsl. Code #:			
				Fineline Code:			

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: