



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

Version 2024		Introduction Type: <input type="text" value="New Item"/>		<input checked="" type="checkbox"/> Final Version		Date: <input type="text" value="2/20/2025"/>																																																											
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																											
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/> Application Number for NDA/ANDA/BLA; PMA/510(k): <input type="text" value="216749"/> Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text" value="11-856-3719"/> Proprietary Name (If Applicable) and Established Name: <input type="text" value="Oxcarbazepine Oral Suspension, USP 300 mg/5 mL"/> Selling Unit NDC: <input type="text" value="31722-687-25"/> UDI <input type="text"/> Description: <input type="text" value="Oxcarbazepine Oral Suspension, USP 300 mg/5 mL"/> Active Ingredient(s): <input type="text" value="Oxcarbazepine, USP"/> URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/> Address: <input type="text" value="800 Centennial Ave, Suite 1"/> City: <input type="text" value="Piscataway"/> Key Contact: <input type="text" value="Customer Service"/> Phone Number: <input type="text" value="1-866-827-3647"/> Product Therapeutic Classification: <input type="text" value="Antiepileptic"/> Application: <input type="text" value="ANDA"/> NDA 505(b) Type: <input type="text" value="NOT APPLICABLE"/> Unit of Use NDC: <input type="text" value="31722-687-25"/> UPC: <input type="text" value="331722687256"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08854"/> Email: <input type="text" value="customerservice@camberpharma.com"/> Fax: <input type="text" value="732-562-8788"/>						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)"/> Other Temperature Range Requirement <input type="text" value="Excursions permitted to 15°C to 30°C (59°F to 86°F)"/> Notes <input type="text"/> 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"/> b. Contact for temperature excursion questions: Name: <input type="text" value="Soma Raju"/> Number: <input type="text" value="732-529-0423"/> Group E-mail: <input type="text" value="somaraju@heterousa.com"/> c. Special regulations for product in any states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Initial shelf life at launch (if different): <input type="text"/> Months																																																											
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																																													
The product is? a legend device? <input type="text" value="No"/> if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="No"/> 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"/> If Unit Dose, indicate NDC here: <input type="text"/> Is the Product... Is the Product... <input type="text" value="Direct-Ship Only Unit of Use"/> Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text" value="Alcohol"/> Country of Origin <input type="text" value="India"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/> Size: <input type="text" value="250 mL"/> Strength: <input type="text" value="300 mg/5 mL"/> Dosage Form: <input type="text" value="Oral suspension"/> Product Shape: <input type="text" value="N/A"/> Product Color: <input type="text" value="Off-white to slightly brown or slightly red"/> Product Imprint: <input type="text" value="N/A"/>																																																																	
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																																											
I. Orange Book Rating: <input type="text" value="AB"/> II. Generic Equivalent to What Brand?: <input type="text" value="Trileptal"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable						Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In What is the NDC selling unit? <input type="text" value="1 Bottle of 250 mL Oral Suspension (Write-in, e.g. 1 Box of 10 Vials)"/> Minimum order quantity? <input type="text" value="Yes"/> If Yes, how many of which package type? <input type="text" value="12"/> Each <input type="text" value="Inner/ Carton/ Pack"/> Inner/ Carton/ Pack <input type="text" value="Case"/> Case																																																											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																																											
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: <input type="text"/> Other exemption - Write in: <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"/> GLN: <input type="text" value="0331722498975"/> GCP: <input type="text"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/>						Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) <input type="text"/> HCPCS J-Code: <input type="text"/> Rx billing unit to pharmacy: <input type="text" value="Each"/> <input type="text" value="Gram"/> <input type="text" value="Milliliter"/>																																																											
GTIN AND HIBCC PRODUCT INFORMATION						ITEM AND PACKING INFORMATION																																																											
<table border="1"><thead><tr><th>Saleable Unit of Measure</th><th>RFID tag(Y/N)</th><th>Saleable Quantity</th><th>HIBCC</th><th>GTIN-14</th><th>Unit of Use GTIN-14</th></tr></thead><tbody><tr><td><input checked="" type="checkbox"/> Item/Each</td><td>N</td><td>1</td><td></td><td>00331722687256</td><td>00331722687256</td></tr><tr><td><input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack</td><td>N</td><td>12</td><td></td><td>30331722687257</td><td></td></tr><tr><td><input type="checkbox"/> Case</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td><input type="checkbox"/> Pallet</td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>						Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	<input checked="" type="checkbox"/> Item/Each	N	1		00331722687256	00331722687256	<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	12		30331722687257		<input type="checkbox"/> Case						<input type="checkbox"/> Pallet						<table border="1"><thead><tr><th>Item/Each:</th><th>Weight Lbs.</th><th>Dimensions (US msmts.) Depth</th><th>Width</th><th>Height</th><th>Volume (Cube)</th><th>Saleable # Pieces</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>1.16</td><td>3</td><td>3</td><td>6.75</td><td>60.75</td><td>1</td></tr><tr><td>Case:</td><td>14.4</td><td>12.25</td><td>9.25</td><td>7.25</td><td>821.52</td><td>12</td></tr><tr><td>Pallet:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces	Box/ Carton/ Bundle/ Inner Pack:	1.16	3	3	6.75	60.75	1	Case:	14.4	12.25	9.25	7.25	821.52	12	Pallet:						
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COST INFORMATION						WHOLESALE USE ONLY:																																																											
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$165.00"/> As of date: <input type="text" value="1/24/2024"/>						Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>																																																											
*Please provide any additional information on page 2.						Signature: <input type="text"/>																																																											

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
Is this product (check all that apply):			
a. Cytotoxic?	<input type="text" value="No"/>		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="text" value="No"/>		
Is the product a CA Prop 65 carcinogen?	<input type="text" value="No"/>		
Is the product a CA Prop 65 reproductive toxicant?	<input type="text" value="No"/>		
Does the product label bear a CA Prop 65 warning?	<input type="text" value="No"/>		
c. Contact Hazard?	<input type="text" value="No"/>		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="text" value="No"/>		
e. Does the product contain DEHP?	<input type="text" value="No"/>		
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text"/>		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text"/>		
Is the product restricted for air shipment? If so, indicate restriction:		<input type="text" value="No"/>	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity? <input type="text" value="No"/>			
RQ Threshold: <input type="text"/>			
Is this a marine pollutant? <input type="text" value="No"/>			
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No (if yes, identify method below)			
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP# <input type="text"/>			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="text" value="No"/>	Controlled Substance Code	<input type="text"/>
Controlled by State(s)?	<input type="text" value="No"/>	Listed Chemical (List I or II)	<input type="text" value="No"/>
ARCOS Reportable?	<input type="text" value="No"/>	If yes, indicate which:	<input type="text"/>
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="text" value="No"/>
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="text" value="Yes"/>	
Restricted to retail pharmacy only:		<input type="text" value="No"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="text" value="No"/>	
Restricted from US territories? (explain in comments)		<input type="text" value="No"/>	
Comments: <input type="text"/>			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			
<input type="text"/>			

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic	<input type="text" value="Corrosive"/>
<input type="checkbox"/> Inorganic	<input type="text" value="Oxidizer"/>
<input type="checkbox"/> Steroid/Androgen	<input type="text" value="Contact Hazard"/>
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text" value="No"/>	
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="text" value="Yes"/>	
If yes, indicate which: <input type="text" value="Group 2 items (non-antineoplastic that meets a hazard criterion)"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="text" value="No"/>	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
Med Guide Required <input type="text" value="No"/>	
Limited Distribution Requirement <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS: <input type="text" value="No"/>	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: <input type="text"/>	
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	DEA #: <input type="text"/>
Site Enrollment Number assigned by Supplier: <input type="text"/>	NCPDP#: <input type="text"/>
	NPI #: <input type="text"/>
Comments <input type="text"/>	
Registry: <input type="text" value="No"/>	
Registry Program Contact Name: <input type="text"/>	Phone: <input type="text"/>
Comments <input type="text"/>	
RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text" value="1-866-827-3647"/>
Is product returnable for credit:	<input type="text" value="Yes"/>
URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/>	
Special regulations or returns requirements for this product in certain states? <input type="text" value="No"/>	
If so, which states? Other requirements? Comments: <input type="text"/>	

Release DATE



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>