



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="3/27/2025"/>																																																														
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																														
<div>Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA; PMA/510(k): <input type="text" value="210030"/> NDA 505(b) Type: <input type="text" value="NOT APPLICABLE"/> 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="Temozolomide Capsules, USP 5 mg"/> Selling Unit NDC: <input type="text" value="31722-411-14"/> Unit of Use NDC: <input type="text" value="31722-411-14"/> UPC: <input type="text" value="331722411141"/> UDI: <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Temozolomide Capsules, USP 5 mg"/> Active Ingredient(s): <input type="text" value="Temozolomide, 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"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08854"/> Phone Number: <input type="text" value="1-866-827-3647"/> Email: <input type="text" value="customerservice@camberpharma.com"/> Product Therapeutic Classification: <input type="text" value="Alkylating agent"/> Fax: <input type="text" value="732-562-8788"/></div>						<div>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 (write in): <input type="text" value="Excursions are permitted between 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? 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: Initial shelf life at launch (if different): <input type="text" value="24"/> Months</div>																																																														
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																																																
<div>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="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"/> If Unit Dose, indicate NDC here: <input type="text"/></div>				<div>Is the Product... Is the Product... <input type="text" value="Direct-Ship Only"/> Orphan Drug Status <input type="text" value="Unit of Use"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text" value="Alcohol, Animal Products, Dairy, Dye, Lactose"/> Country of Origin <input type="text" value="India"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/></div>				<div>Size: <input type="text" value="14 ct"/> Strength: <input type="text" value="5 mg"/> Dosage Form: <input type="text" value="Hard gelatin capsule"/> Product Shape: <input type="text" value="Capsule"/> Product Color: <input type="text" value="Opaque green cap and opaque white body"/> Product Imprint: <input type="text" value="Imprinted with '13' on cap and 'H' on body"/></div>																																																												
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																																														
<div>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="Temodar"/></div>						<div>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 Other: Write In <input type="text"/> What is the NDC selling unit? <input type="text" value="1 Bottle of 14 Capsules"/> (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="24"/> Each <input type="text"/> Inner/ Carton/ Pack <input type="text"/> Case</div>																																																														
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																																														
<div>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"/></div>						<div>Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) HCPCS J-Code: <input type="text" value="J8700"/> Rx billing unit to pharmacy: <input type="text"/> Each <input type="text"/> Gram <input type="text"/> Milliliter</div>																																																														
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<table border="1" style="width:100%; border-collapse: collapse;"><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>00331722411141</td><td>00331722411141</td></tr><tr><td><input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack</td><td>N</td><td>24</td><td></td><td>20331722411145</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		00331722411141	00331722411141	<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	24		20331722411145		<input type="checkbox"/> Case						<input type="checkbox"/> Pallet						<table border="1" style="width:100%; border-collapse: collapse;"><thead><tr><th rowspan="2">Item/Each:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cube)</th><th rowspan="2">Saleable # Pieces</th></tr><tr><th>Depth</th><th>Width</th><th>Height</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.14</td><td>1.7</td><td>1.7</td><td>3</td><td>8.67</td><td>1</td></tr><tr><td>Case:</td><td>3.95</td><td>11</td><td>7.5</td><td>4.5</td><td>371.25</td><td>24</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.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/ Carton/ Bundle/ Inner Pack:	0.14	1.7	1.7	3	8.67	1	Case:	3.95	11	7.5	4.5	371.25	24	Pallet:						
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COST INFORMATION				WHOLESALE USE ONLY:																																																																
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$37.16"/> As of date: <input type="text" value="2/12/2025"/>				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)

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic? ☐ Yes ☐ No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen? ☐ No
Is the product a CA Prop 65 reproductive toxicant? ☐ No
Does the product label bear a CA Prop 65 warning? ☐ No

- c. Contact Hazard? ☐ Yes ☐ No
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) ☐ Yes ☐ No
- e. Does the product contain DEHP? ☐ No ☐ Yes

Is this product regulated for shipment by DOT?
(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 ☐ Yes

Is this product regulated for shipment by IATA?
(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 ☐ Yes

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger ☐ Cargo ☐ Passenger & Cargo

Is this a reportable quantity? ☐ No ☐ Yes

RQ Threshold:

Is this a marine pollutant? ☐ No ☐ Yes

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
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? ☐ No ☐ Yes Controlled Substance Code
- Controlled by State(s)? ☐ No ☐ Yes Listed Chemical (List I or II) ☐ No ☐ Yes
- ARCOS Reportable? ☐ No ☐ Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: ☐ No ☐ Yes

CLASS OF TRADE RESTRICTION:

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:

SDS Hazard Classification

- ☒ 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:

Is the product a NIOSH hazardous drug?

Yes

If yes, indicate which:

Group 1 items (antineoplastic)

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

No

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively: ☐ No ☐ Yes

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

No

Registry Program Contact Name:

Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:

Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?

No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Cytotoxic: Do not open the capsules. If a capsule is damaged, avoid inhalation or contact with your skin, eyes, nose or mucous membranes.

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>