



# 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="3/11/2025"/>																																																														
<b>PRODUCT INFORMATION</b>				<b>SPECIAL HANDLING AND STORAGE REQUIREMENTS*</b>																																																																
<b>Company Name:</b> <input type="text" value="Camber Pharmaceuticals, Inc."/> <b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> <input type="text" value="210500"/> <b>Medical Device Class, if applicable:</b> <input type="text"/> <b>DUNS:</b> <input type="text" value="11-856-3719"/> <b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Dimethyl Fumarate Delayed-Release Capsules 120 mg"/> <b>Selling Unit NDC:</b> <input type="text" value="31722-657-31"/> <b>Unit of Use NDC:</b> <input type="text" value="31722-657-31"/> <b>UPC:</b> <input type="text" value="331722657310"/> <b>CVX Code:</b> <input type="text"/> <b>MVX Code:</b> <input type="text"/> <b>Description:</b> <input type="text" value="Dimethyl Fumarate Delayed-Release Capsules 120 mg"/> <b>Active Ingredient(s):</b> <input type="text" value="Dimethyl fumarate"/> <b>URL for Additional Product Information:</b> <input type="text" value="www.camberpharma.com"/> <b>Address:</b> <input type="text" value="800 Centennial Ave, Suite 1"/> <b>City:</b> <input type="text" value="Piscataway"/> <b>Key Contact:</b> <input type="text" value="Customer Service"/> <b>Phone Number:</b> <input type="text" value="1-866-827-3647"/> <b>Product Therapeutic Classification:</b> <input type="text" value="Fumaric acid derivative (NRF2 activator)"/> <b>State:</b> <input type="text" value="NJ"/> <b>Address 2:</b> <input type="text"/> <b>Zip:</b> <input type="text" value="08854"/> <b>Email:</b> <input type="text" value="customerservice@camberpharma.com"/> <b>Fax:</b> <input type="text" value="732-562-8788"/>				<b>a. Temperature – Indicate the USP temperature range for this product.</b> <b>Temperature Range</b> <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> <b>Other Temperature Range Requirement (write in)</b> <input type="text"/> <b>Notes</b> <input type="text"/> <b>Is this product to be shipped to customers on ice?</b> <input type="text" value="No"/> <b>Is this product to be shipped to customers on dry ice?</b> <input type="text" value="No"/> <b>b. Contact for temperature excursion questions:</b> <b>Name:</b> <input type="text" value="Soma Raju"/> <b>Number:</b> <input type="text" value="732-529-0423"/> <b>Group E-mail:</b> <input type="text" value="somaraju@heterousa.com"/> <b>c. Special regulations for product in any states?</b> <input type="text" value="No"/> <b>Special returns requirements for this product?</b> <input type="text" value="No"/> <b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/> <b>Protect product (unit of sale) from light?</b> <input type="text" value="No"/> <b>e. Shelf life:</b> <input type="text" value="24"/> <b>Months</b> <b>Initial shelf life at launch (if different):</b> <input type="text"/> <b>Months</b>																																																																
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>																																																																
<b>The product is?</b> <b>a legend device?</b> <input type="text" value="No"/> <b>if yes, enter class #</b> <input type="text"/> <b>a product kit?</b> <input type="text" value="No"/> <b>if yes, list NDCs of component parts reverse numbered?</b> <input type="text"/> <b>co-licensed?</b> <input type="text" value="No"/> <b>latex-free?</b> <input type="text" value="Yes"/> <b>preservative-free?</b> <input type="text" value="Yes"/> <b>correctional institution block?</b> <input type="text" value="No"/> <b>opioid?</b> <input type="text" value="No"/> <b>Cannabinoid?</b> <input type="text" value="No"/> <b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b> <input type="text"/> <b>If Unit Dose, indicate NDC here:</b> <input type="text"/>				<b>Is the Product... Is the Product...</b> <input type="text" value="Direct-Ship Only Unit of Use"/> <b>Orphan Drug Status</b> <input type="text"/> <b>FDA Approval Status</b> <input type="text"/> <b>Allergens Present</b> <input type="text" value="Dye, Corn, Alcohol, Animal Products, Sugar, Oats, Spelt"/> <b>Country of Origin</b> <input type="text" value="India"/> <b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="text" value="No"/> <b>Size:</b> <input type="text" value="14 ct"/> <b>Strength:</b> <input type="text" value="120 mg"/> <b>Dosage Form:</b> <input type="text" value="Hard gelatin, delayed-release capsule"/> <b>Product Shape:</b> <input type="text" value="Capsule"/> <b>Product Color:</b> <input type="text" value="Opaque light blue cap and opaque light blue body"/> <b>Product Imprint:</b> <input type="text" value="Imprinted with 'H' on cap and 'D12' on body"/>																																																																
<b>FOR GENERIC DRUG PRODUCTS</b>				<b>ORDER INFORMATION</b>																																																																
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Tecfidera"/> <b>Authorized Generic</b> <input type="checkbox"/> <b>*If Authorized Generic, other section fields are not applicable</b>				<b>Unit of Sale</b> <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input 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 <input type="text"/> <b>What is the NDC selling unit?</b> <input type="text" value="1 Bottle of 14 Capsules (Write-in, e.g. 1 Box of 10 Vials)"/> <b>Minimum order quantity?</b> <input type="text" value="Yes"/> <b>If Yes, how many of which package type?</b> <input type="text" value="24"/> <b>Each</b> <input type="text"/> <b>Inner/ Carton/ Pack</b> <input type="text"/> <b>Case</b>																																																																
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>				<b>PHARMACY ORDER / BILL UNIT</b>																																																																
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/> <b>Is product exempt from DSCSA?</b> <input type="text" value="No"/> <b>If yes, select exemption:</b> <input type="text"/> <b>Other exemption - Write in:</b> <input type="text"/> <b>Is product repackaged?</b> <input type="text" value="No"/> <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="Yes"/> <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/> <b>If yes, attach documentation from FDA.</b> <input type="text"/> <b>GLN:</b> <input type="text" value="0331722498975"/> <b>GCP:</b> <input type="text"/> <b>If yes, was original product purchased direct from mfr?</b> <input type="text"/> <b>Provide source manufacturer for repackaged product</b> <input type="text"/>				<b>Rec. sell unit to customer?</b> <input type="text"/> <b>Rx billing unit to pharmacy:</b> <input type="text" value="Each"/> <b>(Write-in, e.g. 1 Vial)</b> <input type="text"/> <b>HCPCS J-Code:</b> <input type="text"/> <input type="text"/> <b>Gram</b> <input type="text"/> <b>Milliliter</b>																																																																
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<b>Regular Cost</b> <input type="text"/> <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$37.50"/> <b>As of date:</b> <input type="text" value="12/1/2024"/>				<b>Vendor #:</b> <input type="text"/> <b>Whsl. Code #:</b> <input type="text"/> <b>Fineline Code:</b> <input type="text"/>																																																																
<b>*Please provide any additional information on page 2.</b>				<b>Signature:</b> <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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
Is the product a CA Prop 65 carcinogen?   
Is the product a CA Prop 65 reproductive toxicant?   
Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?  
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

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?

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?

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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

### 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
- ☐ Inorganic
- ☐ Steroid/Androgen

Does the product have an Aerosol class? If yes,  
identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

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

#### REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned  
by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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

Version 2024

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><b>Purchase order daily receipt cut off time by supplier</b></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><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></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><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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><b>Class of Trade Restriction:</b></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><b>Other Data Information Required to Process PO:</b></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><b>Return Instructions</b></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><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>