



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

Version 2021		Introduction Type: <input type="text" value="New Item"/>		000 Final Version		Date: <input type="text" value="6/21/2022"/>																								
<b>PRODUCT INFORMATION</b>						<b>SPECIAL HANDLING AND STORAGE REQUIREMENTS*</b>																								
<div>Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="207961"/> Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text" value="82-677-4775"/> Proprietary Name (If Applicable) and Established Name: <input type="text" value="Dabigatran Etexilate Capsules 75mg 60ct"/> Selling Unit NDC: <input type="text" value="31722-621-60"/> Unit of Use NDC: <input type="text"/> UPC: <input type="text" value="331722621601"/> UDI: <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Cream opaque cap / cream opaque body size '2' HPMC capsules imprinted with 'H' on cap and 'D10' on body with black ink filled with mixture of off white to yellowish white pellets"/> Active Ingredient(s): <input type="text" value="Dabigatran Etexilate"/> URL for Additional Product Information: <input type="text"/> Address: <input type="text" value="1031 Centennial Ave (and) 800 Centennial Ave, Suite 1"/> Address 2: <input type="text"/> City: <input type="text" value="Piscataway"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08854"/> 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="Direct Thrombin Inhibitor"/></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"/> 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: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months</div>																								
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>																										
<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 <input type="text"/> reverse numbered? <input type="text" value="No"/> 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... <input type="text" value="Direct-Ship Only"/> Is the Product... <input type="text" value="Unit of Use"/> Orphan Drug Status <input type="text"/>  FDA Approval Status <input type="text"/>  Allergens Present <input type="text"/>  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="60ct"/>  Strength: <input type="text" value="75mg"/>  Dosage Form: <input type="text" value="Oral Solid - Capsule"/>  Product Shape: <input type="text" value="Capsule"/>  Product Color: <input type="text" value="Cream colored, opaque cap and body"/>  Product Imprint: <input type="text" value="'H' on cap and 'D10' on body"/></div>																								
<b>FOR GENERIC DRUG PRODUCTS</b>																														
<div>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="Pradaxa"/></div>																														
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>																														
<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: 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="0331722000000"/> 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>																														
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>																														
<table border="1" style="width:100%; border-collapse: collapse;"><thead><tr><th>Saleable Unit of Measure</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><input type="text" value="1"/></td><td><input type="text"/></td><td><input type="text" value="00331722621601"/></td><td><input type="text"/></td></tr><tr><td><input checked="" type="checkbox"/> Box/Case/Bundle/Inner Pack</td><td><input type="text" value="24"/></td><td><input type="text"/></td><td><input type="text" value="20331722621605"/></td><td><input type="text"/></td></tr><tr><td><input type="checkbox"/> Case</td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><input type="checkbox"/> Pallet</td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr></tbody></table>						Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722621601"/>	<input type="text"/>	<input checked="" type="checkbox"/> Box/Case/Bundle/Inner Pack	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="20331722621605"/>	<input type="text"/>	<input type="checkbox"/> Case	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<b>ORDER INFORMATION</b>																														
<div>Unit of Sale <table border="1" style="width:100%; border-collapse: collapse;"><tr><td><input checked="" type="checkbox"/> Bottle</td><td rowspan="8">What is the NDC selling unit? <input type="text" value="1 bottle of 60 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? <table border="1" style="width:100%; border-collapse: collapse;"><tr><td><input type="text"/></td><td>Each</td></tr><tr><td><input type="text"/></td><td>Inner/Case/Pack</td></tr><tr><td><input type="text" value="1"/></td><td>Case</td></tr></table></td></tr><tr><td><input type="checkbox"/> Box/Case/Bundle/Inner Pack</td></tr><tr><td><input type="checkbox"/> Ampule</td></tr><tr><td><input type="checkbox"/> Glass</td></tr><tr><td><input type="checkbox"/> Tube</td></tr><tr><td><input type="checkbox"/> Vial Liquid Sgl</td></tr><tr><td><input type="checkbox"/> Vial Liquid Multi</td></tr><tr><td><input type="checkbox"/> Vial Powder Sgl</td></tr><tr><td><input type="checkbox"/> Vial Powder Multi</td></tr><tr><td><input type="checkbox"/> Other: Write In</td></tr></table></div>						<input checked="" type="checkbox"/> Bottle	What is the NDC selling unit? <input type="text" value="1 bottle of 60 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? <table border="1" style="width:100%; border-collapse: collapse;"><tr><td><input type="text"/></td><td>Each</td></tr><tr><td><input type="text"/></td><td>Inner/Case/Pack</td></tr><tr><td><input type="text" value="1"/></td><td>Case</td></tr></table>	<input type="text"/>	Each	<input type="text"/>	Inner/Case/Pack	<input type="text" value="1"/>	Case	<input type="checkbox"/> Box/Case/Bundle/Inner Pack	<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								
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**PHARMACY ORDER / BILL UNIT**																																																					
Rec. sell unit to customer?  (Write-in, e.g. 1 Vial)  Rx billing unit to pharmacy:				----------------------	------------		<input type="text"/>	Each		<input type="text"/>	Gram		<input type="text"/>	Milliliter																																							
**ITEM AND PACKING INFORMATION**																																																					
	Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces		-----------------------------	-------------	------------------------	-------	--------	---------------	-------------------				Depth	Width	Height				Box/Case/Bundle/Inner Pack:	0.751	1.97	1.97	4.14		1		Case:	4.41	12.4	8.46	4.72		24		Pallet:	619.5	47.24	39.37	45.59		3072						
**COST INFORMATION**																																																					
Regular Cost  Invoice Cost (WAC) (\$)  As of date:   Vendor #:  Whsl. Code #:  Fineline Code:																																																					
\*Please provide any additional information on page 2. 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. Signature:																																																					



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
<b>Is this product (check all that apply):</b>			
a. Cytotoxic?	<input type="checkbox"/> No		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No		
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No		
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No		
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No		
c. Contact Hazard?	<input type="checkbox"/> No		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No		
e. Does the product contain DEHP?	<input type="checkbox"/> No		
<b>Is this product regulated for shipment by DOT?</b> (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="checkbox"/> No		
<b>Is this product regulated for shipment by IATA?</b> (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="checkbox"/> No		
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
<b>Is this a reportable quantity?</b> <input type="checkbox"/> No			
RQ Threshold: <input type="text"/>			
<b>Is this a marine pollutant?</b> <input type="checkbox"/> No			
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b>			
<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			
<b>Is the Product...</b>			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
Restricted to retail pharmacy only:		<input type="checkbox"/> No	
Restricted to hospital, clinics, and physician offices only:		<input type="checkbox"/> No	
Restricted from US territories? (explain in comments)		<input type="checkbox"/> 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="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/>	
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>	

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

REMS or REGISTRY RESTRICTIONS	
<b>Is there a REMS on this product?</b> <input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
<b>Med Guide Required</b> <input type="checkbox"/> No	
<b>Limited Distribution Requirement</b> <input type="text"/>	
<b>Comments / Details: (For example, iPledge program?)</b> <input type="text"/>	
<b>REMS:</b> <input type="checkbox"/> No	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="text"/>
Wholesale distributor support:	<input type="text"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments <input type="text"/>	
<b>Registry:</b> <input type="checkbox"/> No	
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	1-866-827-3647
Is product returnable for credit:	<input type="checkbox"/> Yes
URL/Link to returns policy: <input type="text"/>	
contact - customerservice@camberpharma.com	
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No	
If so, which states? Other requirements? Comments: <input type="text"/>	



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

Version 2021

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="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></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="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></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="text"/></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="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: 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="text"/></p> <p>Other fees apply: <input type="text"/></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="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></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="text"/></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="text"/></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="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>