



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

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>Company Name:</b> <input type="text" value="Camber Pharmaceuticals, Inc."/> <b>Application:</b> <input type="text" value="ANDA"/> <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="215523"/> <b>Medical Device Class, if applicable:</b> <input type="text"/> <b>DUNS:</b> <input type="text" value="82-677-4775"/> <b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Dexmethylphenidate HCl ER 30mg 100ct"/> <b>Selling Unit NDC:</b> <input type="text" value="31722-234-01"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="331722234016"/> <b>UDI</b> <input type="text"/> <b>CVX Code:</b> <input type="text"/> <b>MVX Code:</b> <input type="text"/> <b>Description:</b> <input type="text" value="Oral solid capsule, capsule shaped, white/white, M30 and AC"/> <b>Active Ingredient(s):</b> <input type="text" value="Dexmethylphenidate Hydrochloride"/> <b>URL for Additional Product Information:</b> <input type="text"/> <b>Address:</b> <input type="text" value="1031 Centennial Ave (and) 800 Centennial Ave, Suite 1"/> <b>Address 2:</b> <input type="text"/> <b>City:</b> <input type="text" value="Piscataway"/> <b>State:</b> <input type="text" value="NJ"/> <b>Zip:</b> <input type="text" value="08854"/> <b>Key Contact:</b> <input type="text" value="Customer Service"/> <b>Email:</b> <input type="text" value="customerservice@camberpharma.com"/> <b>Phone Number:</b> <input type="text" value="1-866-827-3647"/> <b>Fax:</b> <input type="text" value="732-562-8788"/> <b>Product Therapeutic Classification:</b> <input type="text"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b> 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>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"/> Special returns requirements for this product? <input type="text" value="No"/> <b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/> <b>e. Shelf life:</b> <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> Initial shelf life at launch (if different): <input type="text" value="24"/> Months <input type="text" value="24"/> Months	
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is it 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"/> 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" value="No"/> If Unit Dose, indicate NDC here: <input type="text"/>		<b>Is the Product... Direct-Ship Only</b> <input type="text"/> <b>Is the Product... Neither</b> <input type="text"/> <b>Orphan Drug Status</b> <input type="text"/> <b>FDA Approval Status</b> <input type="text"/> <b>Allergens Present</b> <input type="text"/> <b>Country of Origin</b> <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>	
		<b>Size:</b> <input type="text" value="100ct"/> <b>Strength:</b> <input type="text" value="30mg"/> <b>Dosage Form:</b> <input type="text" value="Oral Solid - Capsule"/> <b>Product Shape:</b> <input type="text" value="Capsule Shaped"/> <b>Product Color:</b> <input type="text" value="White/White"/> <b>Product Imprint:</b> <input type="text" value="M30 and AC"/>	
ORDER INFORMATION			
<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 Power 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 100 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"/> Each <input type="text"/> Inner/ Carton/Pack <input checked="" type="text" value="x"/> Case	
FOR GENERIC DRUG PRODUCTS			
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Focalin XR"/>		*If Authorized Generic, other section fields are not applicable	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION			
<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="No"/> <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="0331722000000"/> <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"/>	
GTIN AND HIBCC PRODUCT INFORMATION			
<b>Saleable Unit of Measure</b> <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		<b>Saleable Quantity</b> <input type="text" value="1"/> <b>HIBCC</b> <input type="text"/> <b>GTIN-14</b> <input type="text" value="00331722234016"/> <input type="text" value="10331722234013"/> <b>Unit of Use GTIN-14</b> <input type="text"/>	
COST INFORMATION		WHOLESALE USE ONLY:	
<b>Regular Cost</b> <input type="text"/> <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$128.00"/> <b>As of date:</b> <input type="text"/>		<b>Vendor #:</b> <input type="text"/> <b>Whsl. Code #:</b> <input type="text"/> <b>Fineline Code:</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.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																																																									
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            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</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/></p> <p>RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> (if yes, identify method below)</p> <p><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"/></p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #2c4e64; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">SDS Hazard Classification</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; padding: 2px;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; padding: 2px;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Inorganic</td> <td style="padding: 2px;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Steroid/Androgen</td> <td style="padding: 2px;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Does the product have an Aerosol class? 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<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> Yes      Controlled Substance Code <input type="text" value="1724"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No      Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/></p> <p>Schedule No. <input type="text" value="2"/>      If yes, indicate which: <input type="text"/></p> <p>Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #2c4e64; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">RETURN INSTRUCTIONS</th> </tr> </thead> <tbody> <tr> <td style="width: 60%; padding: 2px;">Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/></td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Is product returnable for credit: <input type="checkbox"/> Yes</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></td> <td style="padding: 2px;"></td> </tr> <tr> <td colspan="2" style="padding: 2px;">Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</td> </tr> <tr> <td colspan="2" style="padding: 2px;">If so, which states? Other requirements? Comments? <input type="text"/></td> </tr> </tbody> </table>	RETURN INSTRUCTIONS		Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/>		Is product returnable for credit: <input type="checkbox"/> 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="checkbox"/> No		If so, which states? Other requirements? Comments? <input type="text"/>																																													
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<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #2c4e64; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="padding: 2px; height: 40px;"><input type="text"/></td> </tr> </tbody> </table>	MISCELLANEOUS NOTES and/or Image of Product Barcode:		<input type="text"/>																																																					
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# 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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>