



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 211009
Medical Device Class, if applicable:
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Methylphenidate Hydrochloride Extended-Release Tablets, USP 18 mg
Selling Unit NDC: 31722-952-01 **Unit of Use NDC:** **UPC:** 331722952019
UDI **CVX Code:** **MXV Code:**
Description: Methylphenidate Hydrochloride Extended-Release Tablets, USP 18 mg
Active Ingredient(s): Methylphenidate hydrochloride, USP
URL for Additional Product Information: www.camberpharma.com
Address: 800 Centennial Ave, Suite 1 **Address 2:**
City: Piscataway **State:** NJ **Zip:** 08854
Key Contact: Customer Service **Email:** customerservice@camberpharma.com
Phone Number: 1-866-827-3647 **Fax:** 732-562-8788
Product Therapeutic Classification: Central nervous system (CNS) stimulant

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
b. Contact for temperature excursion questions:
Name: Soma Raju
Number: 732-529-0423
Group E-mail: somaraju@heterousa.com
c. Special regulations for product in any states?
 Special returns requirements for this product?
d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?
e. Shelf life: Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Dye, Corn, Alcohol"/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="USA"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
correctional institution block? 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"/>		
		Size:	<input type="text" value="100 ct"/>
		Strength:	<input type="text" value="18 mg"/>
		Dosage Form:	<input type="text" value="Extended-release, film coated tablet"/>
		Product Shape:	<input type="text" value="Round, cylindrical, biconvex"/>
		Product Color:	<input type="text" value="Light yellow to yellow"/>
		Product Imprint:	<input type="text" value="Printed with '212' in black ink"/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 100 Tablets"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	

Minimum order quantity?
 If Yes, how many of which package type?
 Each
 Inner/ Carton/ Pack
 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged?
 Is product sold by manufacturer's exclusive distributor?
 Has FDA granted waiver/exception/exemption for product?
 If yes, attach documentation from FDA.
 GLN:
 GCP:
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.11	1.76	1.76	2.98	9.25	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	3.2	11	7.5	3.2	264.00	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722952019	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722952016	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:
 Vendor #:
 Whsl. Code #:
 Finline Code:

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:

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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"/></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"/></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 & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No 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"/> No (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>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> No If Yes, is it managed with a pharmacy registry? <input type="checkbox"/> Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No Limited Distribution Requirement <input type="checkbox"/> Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> No REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="checkbox"/> Wholesale distributor support: <input type="checkbox"/> Provider Name: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/> No Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments: <input type="text"/></p> </div>	<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
<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						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No Controlled Substance Code <input type="text" value="1724"/></p> <p>Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text" value="2"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes <input type="checkbox"/> No</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>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> <p>DEA Form 222 or its electronic equivalent is required for all returns in all states.</p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<p>*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.</p>							



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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
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"/>	Purchase order daily receipt cut off time by supplier 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"/>	Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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 Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>