



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

Version 2024

Introduction Type: ☒ Final VersionDate:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc. Application Number for NDA/ANDA/BLA; PMA/510(k): 211009 Medical Device Class, if applicable: DUNS: 11-856-3719 Proprietary Name (If Applicable) and Established Name: Methylphenidate Hydrochloride Extended-Release Tablets, USP 27 mg Selling Unit NDC: 31722-953-01 UDI Description: Methylphenidate Hydrochloride Extended-Release Tablets, USP 27 mg Active Ingredient(s): Methylphenidate hydrochloride, USP URL for Additional Product Information: www.camberpharma.com Address: 800 Centennial Ave, Suite 1 City: Piscataway Key Contact: Customer Service Phone Number: 1-866-827-3647 Product Therapeutic Classification: Central nervous system (CNS) stimulant Application: ANDA NDA 505(b) Type: NOT APPLICABLE Unit of Use NDC: CVX Code: UPC: 331722953016 MVX Code: Address 2: State: NJ Zip: 08854 Email: customerservice@camberpharma.com Fax: 732-562-8788				a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) Other Temperature Range Requirement (write in) Notes Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No 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? *Yes Special returns requirements for this product? *Yes d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No e. Shelf life: 24 Months Initial shelf life at launch (if different): Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? No opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:		Is the Product... Is the Product... Direct-Ship Only Orphan Drug Status Neither FDA Approval Status Allergens Present Dye, Corn, Alcohol Country of Origin USA Is this product covered under the Trade Agreements Act (TAA)? Yes		Size: 100 ct Strength: 27 mg Dosage Form: Extended-release, film coated tablet Product Shape: Round, cylindrical, biconvex Product Color: Light pink to pink Product Imprint: Printed with '1213' in black ink			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB ☐ Authorized Generic ☐ *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Concerta							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No If yes, select exemption: Other exemption - Write in: Is product repackaged? No Is product sold by manufacturer's exclusive distributor? Yes Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA.		GLN: 0843368117603 GCP: If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product					
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14		
☒ Item/Each	N	1		00331722953016			
☒ Box/ Carton/ Bundle/ Inner Pack							
☒ Case	N	24		10331722953013			
☐ Pallet							
ITEM AND PACKING INFORMATION							
	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:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost Invoice Cost (WAC) (\$) \$74.75 As of date: 9/1/2021				Vendor #: Whsl. Code #: Fineline 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

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? | <input type="text" value="Yes"/> | Controlled Substance Code | <input type="text" value="1724"/> |
| Controlled by State(s)? | <input type="text" value="Yes"/> | Listed Chemical (List I or II) | <input type="text" value="No"/> |
| ARCOS Reportable? | <input type="text" value="Yes"/> | If yes, indicate which: | <input type="text"/> |
| Schedule No. | <input type="text" value="2"/> | Is it a scheduled listed chemical product?: | <input type="text" value="No"/> |

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 | <input type="text" value="Corrosive"/> |
| ☐ Inorganic | <input type="text" value="Oxidizer"/> |
| ☐ Steroid/Androgen | <input type="text" value="Contact Hazard"/> |

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:

Phone:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned

by Supplier:

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?

DEA Form 222 or its electronic equivalent is required for all returns in all states.

MISCELLANEOUS NOTES and/or Image of Product Barcode:

*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

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
Purchase orders may be accepted by: a. EDI ☐ b. Autofax ☐ c. Fax ☐ d. Phone only ☐ e. Supplier Web Site only ☐ Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: ☐ Ships for second day receipt: ☐ Ships regular ground for 3-10 days receipt: ☐
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions Contact # if product is 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:	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? ☐ Is product order for restocking purposes? ☐