



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

Version 2021 Introduction Type: New Item Final Version Date: 6/4/2024

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): 214959
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (If Applicable) and Established Name: Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) 30 mg
 Selling Unit NDC: 31722-195-01 Unit of Use NDC: UPC: 331722195010
 UDI CVX Code: MVX Code:
 Description: Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) 30 mg
 Active Ingredient(s): Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, USP, and amphetamine sulfate, 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: Controlled Room – between 20 and 25 C (68° – 77° F)
 Other Temperature Range Requirement (write in): Excursions permitted to 15° to 30°C (59° to 86°F)
 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: Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size: 100 ct	
if yes, enter class # a product kit? <input type="checkbox"/> No	Is the Product... Orphan Drug Status <input type="checkbox"/>	Strength: 30 mg	
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status <input type="checkbox"/>	Dosage Form: Extended-release, hard gelatin capsule	
co-licensed? <input type="checkbox"/> No	Allergens Present	Product Shape: Capsule	
latex-free? <input type="checkbox"/> Yes	Dye, Corn, Alcohol, Animal, Sugar	Product Color: Yellow opaque cap and white opaque body	
preservative-free? <input type="checkbox"/> Yes	Country of Origin: USA	Product Imprint: Imprinted with '30 mg' on cap and 'T' on body in black ink	
correctional institution block? opioid? <input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		
Cannabinoid? <input type="checkbox"/> No			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			
If Unit Dose, indicate NDC here: <input type="checkbox"/>			

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 100 Capsules
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> 24 Each
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Inner/ Carton/Pack
	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB1 Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Adderall XR

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? Yes No
 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: 0860000397957
 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		
Box/ Carton/ Bundle/ Inner Pack:	0.15	2.22	2.22	3.84	18.82	1
Case:	4.1	14.5	10.1	4.5	659.03	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		00331722195010	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722195017	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$) \$70.00
 As of date: 10/25/2021
 Vendor #:
 Whsl. Code #:
 Finline Code:



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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? No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

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? No

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? No

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

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

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

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments) No

Comments:

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.

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"/>	<input type="checkbox"/> No
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/>	<input type="checkbox"/> No

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

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

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 <input type="checkbox"/> No	
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"/> Yes <input type="checkbox"/> No	
If so, which states? Other requirements? Comments? <input type="text"/>	
DEA Form 222 or its electronic equivalent is required for all returns in all states. <input type="checkbox"/>	



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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"/>	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: <input type="text"/> 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:	
<input type="text"/>	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>