



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 7/22/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 213709

**Medical Device Class, if applicable:**

**DUNS:** 11-856-3719

**Proprietary Name (If Applicable) and Established Name:** Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single-Entity Amphetamine Product) 7.5 mg

**Selling Unit NDC:** 31722-156-01 **Unit of Use NDC:** **UPC:** 331722156011

**UDI** **CVX Code:** **MVX Code:**

**Description:** Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single-Entity Amphetamine Product) 7.5 mg

**Active Ingredient(s):** Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, USP, and amphetamine sulfate, USP

**URL for Additional Product Information:** [www.camberpharma.com](http://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](mailto:customerservice@camberpharma.com)

**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788

**Product Therapeutic Classification:** Central nervous system (CNS) stimulant

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**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](mailto:somaraju@heterousa.com)

**c. Special regulations for product in any states?**

Special returns requirements for this product?  \*Yes  \*Yes

**d. Store product (unit of sale) upright?**  No

**e. Shelf life:** **Protect product (unit of sale) from light?**  No

**Initial shelf life at launch (if different):**  24 **Months**  Months

## ADDITIONAL PRODUCT 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... Direct-Ship Only**

**Is the Product... Neither**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

Corn, Alcohol, Sugar

**Country of Origin** USA

**Is this product covered under the Trade Agreements Act (TAA)?**  Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 100 ct

**Strength:** 7.5 mg

**Dosage Form:** Tablet

**Product Shape:** Oval

**Product Color:** Light blue

**Product Imprint:** One side debossed with T371 with two partial bisects and other side with two partial bisects and one full bisect

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In

**What is the NDC selling unit?** 1 Bottle of 100 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

24 Each

Inner/Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:** AB

**II. Generic Equivalent to What Brand?:** Adderall

## 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

**Is product exempt from DSCSA?**  No

**GLN:** 0860000397957

**GCP:**

**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.**

**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:	0.07	1.52	1.52	2.69	6.21	1
Case:	2.1	9.8	6.5	3	191.1	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		00331722156011	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722156018	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)** \$37.28

**As of date:** 8/12/2021

**WHOLESALE USE ONLY:**

**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:



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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  No
- 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"/>	
<b>REMS:</b>	
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"/>	
<b>Registry:</b>	
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"/>	



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

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