



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

Version 2021 Introduction Type: New Item 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): 214959
Medical Device Class, if applicable:
DUNS: 82-677-4775
Proprietary Name (If Applicable) and Established Name: Amphetamine ER Capsule 10mg 100ct
Selling Unit NDC: 31722-186-01 **Unit of Use NDC:**
UDI: **CVX Code:** **UPC:** 331722186018
MXV Code:
Description: Oral Solid - Capsule, Capsule Shaped, Blue / Blue, 10 mg and T
Active Ingredient(s): Dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate and amphetamine aspartate
URL for Additional Product Information:
Address: 1031 Centennial Ave (and) 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:

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? No
 Special returns requirements for this product? No
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? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size: 100ct
if yes, enter class # a product kit? <input type="checkbox"/> No	Is the Product... Orphan Drug Status <input type="checkbox"/>	
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status <input type="text"/>	Strength: 10mg
co-licensed? <input type="checkbox"/> No	Allergens Present <input type="text"/>	Dosage Form: Oral Solid - Capsule
latex-free? <input type="checkbox"/> Yes	Country of Origin: USA <input type="checkbox"/>	Product Shape: Capsule Shaped
preservative-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/>	Product Color: Blue / Blue
correctional institution block? <input type="checkbox"/> No		Product Imprint: 10 mg and T
opioid? <input type="checkbox"/> No		
Cannabinoid? <input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No		
If Unit Dose, indicate NDC here: <input type="text"/>		

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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> 24 Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In <input type="text"/>	<input type="text"/> 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 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 No
Has FDA granted waiver/exception/exemption for product? No
If yes, attach documentation from FDA.
GLN: 0331722000000
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:	0.936		1.876	3.225	0	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2.6	12.3	8.3	3.8	387.942	24
Pallet:					0	

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		00331722186018	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722186015	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
Invoice Cost (WAC) (\$) \$70.00
As of date:
Vendor #:
Whsl. Code #:
Fineline Code:

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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) No

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) No

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: No

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?
 (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 9193

Controlled by State(s)? Yes No Listed Chemical (List I or II) No

ARCOS Reportable? Yes No If yes, indicate which:

Schedule No. 2 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:

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen 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? No
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
 If Yes, is it managed with a pharmacy registry?
 Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes No

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

