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

Version 2024		Introduction Type:	New Item	DRAFT Final Version	Date:	2/2/2026

PRODUCT INFORMATION

Field	Value
Company Name:	Camber Pharmaceuticals, Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	210523
NDA 505(b) Type:	NOT APPLICABLE
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Sodium Oxybate Oral Solution 0.5 g/mL
Selling Unit NDC:	31722-891-18
Unit of Use NDC:	31722-891-18
UPC:	331722891189
UDI	
CVX Code:	
MVX Code:	
Description:	Sodium Oxybate Oral Solution 0.5 g/mL
Active Ingredient(s):	Sodium oxybate
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 depressant

ADDITIONAL PRODUCT INFORMATION

Field	Value
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…	Unit of Use
Orphan Drug Status	
FDA Approval Status	
Allergens Present	Alcohol
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION

Field	Value
Size:	180 mL
Strength:	0.5 g/mL
Dosage Form:	Clear to slightly opalescent oral solution
Product Shape:	N/A
Product Color:	Colorless
Product Imprint:	N/A

FOR GENERIC DRUG PRODUCTS

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Field	Value
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
GLN:	0843368117603
GCP:	
Is product repackaged?	No
If yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	Yes
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	
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
x Item/Each	N	1		00331722891189	00331722891189
Box/Carton/Bundle/Inner Pack					
x Case	N	12		10331722891186	
Pallet					

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Field	Value
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:

Field	Value
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com

Field	Value
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

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
x	Bottle	1 Bottle of 180 mL Oral Solution
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
	Ampule	
	Glass	Minimum order quantity? Yes
	Tube	
	Vial Liquid Sgl	
	Vial Liquid Multi	If Yes, how many of which package type?
	Vial Powder Sgl	12 Each
	Vial Powder Multi	Inner/Carton/Pack
	Other: Write In	Case

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.56	2.75	2.75	5.75	43.48	1
Box/Carton/Bundle/Inner Pack:						
Case:	7.4	13	9.8	6.5	828.1	12
Pallet:						

COST INFORMATION

Field	Value
Regular Cost	
Invoice Cost (WAC) ($)	$5,268.73
As of date:	1/19/2026

WHOLESALER USE ONLY:

Field	Value
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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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? — No
  - (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? — No

Is this product regulated for shipment by DOT? — No
(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? — No
(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: — 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? — 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#

SDS Hazard Classification

[x] Organic	[ ] Corrosive
[ ] Inorganic	[ ] Oxidizer
[ ] Steroid/Androgen	[ ] Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: — No
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? — Yes
If Yes, is it managed with a pharmacy registry? — Yes
Website URL: www.SOXREMSProgram.com

Med Guide Required — Yes
Limited Distribution Requirement — Yes
Comments / Details: (For example, iPledge program?) — Sodium Oxybate Shared System REMS Program

REMS: — Yes
- REMS Program Manager Name: Syneos Health — Phone: 1-833-769-7367
- Supplier Manages REMS registry exclusively: No
- Wholesale distributor support: No
- Provider Name: — DEA #:
- Site Enrollment Number assigned — NCPDP#:
- by Supplier: — NPI #:
- Comments

Registry: — Yes
- Registry Program Contact Name: REMS Call Center — Phone: 1-833-769-7367
- Comments

ADD'L STORAGE INFORMATION

Is the Product…
Controlled Substance?	Yes	Controlled Substance Code	2012
Controlled by State(s)?	Yes	Listed Chemical (List I or II)	No
ARCOS Reportable?	Yes	If yes, indicate which:	
Schedule No.	3	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 — 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: Distribution to Enrolled Wholesalers-Distributors or Certified Specialty Pharmacies only

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647
Is product returnable for credit: — Yes
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:

Product comes with press in bottle adapter and oral measuring device (plastic syringe).

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Version 2024   **FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI		
b. Autofax	Fax Number:	
c. Fax	Fax Number:	
d. Phone only	Phone No.:	
e. Supplier Web Site only	Site Address:	

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #:   Name:

Phone:

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:

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:

Miscellaneous Notes:

Standard Order Receipt and Processing

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:

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:

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?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?