



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

Version 2021

Introduction Type: ☒ Post Launch Change☒ Final Version

Date: 6/23/2024

| PRODUCT INFORMATION | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | |
|---|--|--|--|---|--|--|--|
| Company Name: Camber Pharmaceuticals, Inc. Application: ANDA | | | | a. Temperature – Indicate the USP temperature range for this product. | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 207420 | | | | Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F) | | | |
| Medical Device Class, if applicable: | | | | Other Temperature Range Requirement (write in): <input type="text"/> | | | |
| DUNS: 11-856-3719 | | | | Notes: <input type="text"/> | | | |
| Proprietary Name (If Applicable) and Established Name: Omega-3-Acid Ethyl Esters Capsules, USP 1 gram | | | | Is this product to be shipped to customers on ice? <input type="text"/> No | | | |
| Selling Unit NDC: 31722-936-12 Unit of Use NDC: 31722-936-12 UPC: 331722936125 | | | | Is this product to be shipped to customers on dry ice? <input type="text"/> No | | | |
| UDI | | | | b. Contact for temperature excursion questions: | | | |
| Description: Omega-3-Acid Ethyl Esters Capsules, USP 1 gram | | | | Name: Soma Raju | | | |
| Active Ingredient(s): Omega-3-acid ethyl esters, USP | | | | Number: 732-529-0423 | | | |
| URL for Additional Product Information: www.camberpharma.com | | | | Group E-mail: somaraju@heterousa.com | | | |
| Address: 800 Centennial Ave, Suite 1 | | | | c. Special regulations for product in any states? | | | |
| City: Piscataway | | | | Special returns requirements for this product? <input type="text"/> No | | | |
| Key Contact: Customer Service | | | | d. Store product (unit of sale) upright? | | | |
| Phone Number: 1-866-827-3647 | | | | Protect product (unit of sale) from light? <input type="text"/> No | | | |
| Product Therapeutic Classification: Antihyperlipidemic | | | | e. Shelf life: | | | |
| | | | | Initial shelf life at launch (if different): <input type="text"/> 24 Months | | | |
| | | | | | | | |
| ADDITIONAL PRODUCT INFORMATION | | | | PRODUCT DESCRIPTION INFORMATION | | | |
| The product is? | | | | Size: 120 ct | | | |
| a legend device? <input type="text"/> No | | | | Strength: 1 gm | | | |
| if yes, enter class # | | | | Dosage Form: Clear, transparent capsules | | | |
| a product kit? <input type="text"/> No | | | | Product Shape: Oblong | | | |
| if yes, list NDCs of component parts | | | | Product Color: Clear (colorless) to light yellow | | | |
| reverse numbered? <input type="text"/> No | | | | Product Imprint: Imprinted with 'AT 132' in white ink | | | |
| co-licensed? <input type="text"/> No | | | | | | | |
| latex-free? <input type="text"/> Yes | | | | | | | |
| preservative-free? <input type="text"/> Yes | | | | | | | |
| correctional institution block? <input type="text"/> No | | | | | | | |
| opioid? <input type="text"/> No | | | | | | | |
| Cannabinoid? <input type="text"/> No | | | | | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> | | | | | | | |
| If Unit Dose, indicate NDC here: <input type="text"/> | | | | | | | |
| Is the Product... <input type="text"/> Direct-Ship Only | | | | | | | |
| Is the Product... <input type="text"/> Unit of Use | | | | | | | |
| Orphan Drug Status | | | | | | | |
| FDA Approval Status | | | | | | | |
| Allergens Present | | | | | | | |
| Soy, Alcohol | | | | | | | |
| Country of Origin <input type="text"/> USA | | | | | | | |
| Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> Yes | | | | | | | |
| FOR GENERIC DRUG PRODUCTS | | | | | | | |
| I. Orange Book Rating: <input type="text"/> AB <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable | | | | | | | |
| II. Generic Equivalent to What Brand?: <input type="text"/> Lovaza | | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | |
| Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Yes | | | | | | | |
| Is product exempt from DSCSA? <input type="text"/> No | | | | | | | |
| GLN: 00331722498975 | | | | | | | |
| If yes, select exemption: | | | | | | | |
| Other exemption - Write in: | | | | | | | |
| Is product repackaged? <input type="text"/> No | | | | | | | |
| Is product sold by manufacturer's exclusive distributor? <input type="text"/> Yes | | | | | | | |
| Has FDA granted waiver/exception/exemption for product? <input type="text"/> No | | | | | | | |
| If yes, attach documentation from FDA. | | | | | | | |
| GCP: | | | | | | | |
| If yes, was original product purchased direct from mfr? <input type="text"/> | | | | | | | |
| Provide source manufacturer for repackaged product | | | | | | | |
| GTIN AND HIBCC PRODUCT INFORMATION | | | | | | | |
| Saleable Unit of Measure | | | | | | | |
| Saleable Quantity | | | | | | | |
| HIBCC | | | | | | | |
| GTIN-14 | | | | | | | |
| Unit of Use GTIN-14 | | | | | | | |
| Item/Each | | | | | | | |
| Box/Carton/Bundle/Inner Pack | | | | | | | |
| Case | | | | | | | |
| Pallet | | | | | | | |
| Regular Cost | | | | | | | |
| Invoice Cost (WAC) (\$) | | | | | | | |
| As of date: 7/1/2020 | | | | | | | |
| Vendor #: | | | | | | | |
| Whsl. Code #: | | | | | | | |
| Fineline Code: | | | | | | | |
| Signature: | | | | | | | |

*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?
- 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?

- (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="No"/> | Controlled Substance Code | <input type="text"/> |
| Controlled by State(s)? | <input type="text" value="No"/> | Listed Chemical (List I or II) | <input type="text" value="No"/> |
| ARCOS Reportable? | <input type="text" value="No"/> | If yes, indicate which: | <input type="text"/> |
| Schedule No. | <input type="text" value="No"/> | 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

- | | |
|---|--|
| <input checked="" type="checkbox"/> Organic | <input type="text" value="No"/> Corrosive |
| <input type="checkbox"/> Inorganic | <input type="text" value="No"/> Oxidizer |
| <input type="checkbox"/> Steroid/Androgen | <input type="text" value="No"/> 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:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name:

Comments

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:

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 |
|---|---|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p> |
| <p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p> | <p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p> |
| <p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p> | |
| <p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| <p>Miscellaneous Notes:</p> <p><input type="text"/></p> | <p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p> |