



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): 204596
Medical Device Class, if applicable: _____
DUNS: 82-677-4775
Proprietary Name (If Applicable) and Established Name: Fenofibrate Tabs 48Mg 90Ct
Selling Unit NDC: 31722-595-90 **Unit of Use NDC:** 31722-595-90 **UPC:** 33172259502
UDI: N/A **CVX Code:** _____ **MXV Code:** NA
Description: Yellow, Oval Shaped Tablet embossed with 'J' on upper punch and '137' on lower
Active Ingredient(s): _____
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:
 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: 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: <input type="text" value="90"/> | |
| if yes, enter class # a product kit? _____ | Is the Product... Orphan Drug Status <input type="checkbox"/> | Strength: <input type="text" value="48mg"/> | |
| if yes, list NDCs of component parts reverse numbered? _____ | FDA Approval Status <input type="text"/> | Dosage Form: <input type="text" value="Oral Solid Tablet"/> | |
| co-licensed? <input type="checkbox"/> No | Allergens Present <input type="text"/> | Product Shape: <input type="text" value="Oval"/> | |
| latex-free? <input type="checkbox"/> No | Country of Origin <input type="text" value="India"/> | Product Color: <input type="text" value="Yellow"/> | |
| preservative-free? <input type="checkbox"/> No | Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> | Product Imprint: <input type="text" value="J/137"/> | |
| correctional institution block? <input type="checkbox"/> No | | | |
| 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"/> | | | |
| If Unit Dose, indicate NDC here: _____ | | | |

ORDER INFORMATION

| Unit of Sale | What is the NDC selling unit? |
|--|--|
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 bottle of 90ct"/> |
| <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" value="24"/> Each |
| <input type="checkbox"/> Vial Power Multi | <input type="text"/> Inner/ Carton/Pack |
| <input type="checkbox"/> Other: Write In _____ | <input type="text"/> Case |

FOR GENERIC DRUG PRODUCTS

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

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?
 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:
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: | 0.1 | | 1.5 | 3 | 0 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | 0 | |
| Case: | 2.95 | 9.5 | 6.5 | 4.25 | 0.15 | 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 | | 00331722595902 | 00331722595902 |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 24 | | 20331722595906 | |
| <input type="checkbox"/> Pallet | | | | |

COST INFORMATION **WHOLESALE USE ONLY:**

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



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Version 2021

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?
 - Does the product label bear a CA Prop 65 warning?
- 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?

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

CLASS OF TRADE RESTRICTION:

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

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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: NA Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
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: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #: No Yes
Site Enrollment Number assigned by Supplier: NCPDP#: No Yes
NPI #: No Yes

Comments

Registry: No Yes
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 Yes
If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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> <ul style="list-style-type: none"> a. EDI <input style="width: 100px;" type="text"/> b. Autofax <input style="width: 100px;" type="text"/> Fax Number: <input style="width: 150px;" type="text"/> c. Fax <input style="width: 100px;" type="text"/> Fax Number: <input style="width: 150px;" type="text"/> d. Phone only <input style="width: 100px;" type="text"/> Phone No.: <input style="width: 150px;" type="text"/> e. Supplier Web Site only <input style="width: 100px;" type="text"/> Site Address: <input style="width: 150px;" type="text"/> <p>Minimum Order Quantity: <input style="width: 200px;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 200px;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 200px;" type="text"/> Phone: <input style="width: 200px;" type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 150px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input style="width: 100px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100px;" type="text"/></p> <p>Comments: <input style="width: 400px; height: 60px;" type="text"/></p> | <p>Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 200px;" 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 style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 100px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 100px;" type="text"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></p> |
| Class of Trade Restriction: | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 400px; height: 30px;" type="text"/></p> | |
| Other Data Information Required to Process PO: | Return Instructions |
| <p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 200px;" type="text"/></p> <p>Physician/Clinic Phone # <input style="width: 200px;" type="text"/></p> <p>Physician State License # <input style="width: 200px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 200px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 200px;" type="text"/></p> | <p>Contact # if product is received damaged: <input style="width: 100px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 200px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 400px; height: 40px;" type="text"/></p> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <p><input style="width: 450px; height: 100px;" type="text"/></p> | <p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p> |