



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

Version 2021 Introduction Type: 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): 215767
Medical Device Class, if applicable:
DUNS: 82-677-4775
Proprietary Name (If Applicable) and Established Name: Famotidine Tablets USP, 40mg 500ct
Selling Unit NDC: 31722-018-05 **Unit of Use NDC:** **UPC:** 331722018050
UDI **CVX Code:** **MVX Code:**
Description: Oral Solid - Tablet, Round Shaped, White, '12' and 'T'
Active Ingredient(s): Famotidine
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?
 Is this product to be shipped to customers on dry ice?
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?
 Special returns requirements for this product?
d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?
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="text" value="No"/> | Is the Product... Direct-Ship Only <input type="text"/> | Size: 500ct | |
| if yes, enter class # <input type="text"/> | Is the Product... Neither <input type="text"/> | Strength: 40mg | |
| a product kit? <input type="text" value="No"/> | Orphan Drug Status <input type="text"/> | Dosage Form: Oral Solid - Tablet | |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/> | FDA Approval Status <input type="text"/> | Product Shape: Round | |
| co-licensed? <input type="text" value="No"/> | Allergens Present <input type="text"/> | Product Color: White | |
| latex-free? <input type="text" value="Yes"/> | Country of Origin: India <input type="text"/> | Product Imprint: '12' and 'T' | |
| preservative-free? <input type="text" value="Yes"/> | Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/> | | |
| correctional institution block? <input type="text" value="No"/> | | | |
| opioid? <input type="text" value="No"/> | | | |
| Cannabinoid? <input type="text" value="No"/> | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text" value="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 500 tablets |
| <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="text" value="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 | 24 Each |
| <input type="checkbox"/> Vial Power Multi | Inner/ Carton/Pack |
| <input type="checkbox"/> Other: Write In | 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?
Rx billing unit to pharmacy:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged?
 Is product sold by manufacturer's exclusive distributor?
 Has FDA granted waiver/exception/exemption for product?
 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 | | |
| Box/ Carton/ Bundle/ Inner Pack: | 0.1 | | 1.625 | 2.625 | 0 | 1 |
| Case: | 2.5 | 9.75 | 7 | 4 | | 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 | | 00331722018050 | |
| <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 24 | | 20331722018054 | |
| <input type="checkbox"/> Pallet | | | | |

COST INFORMATION **WHOLESALE USE ONLY:**

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