



# 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:**  **Application:**   
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):**   
**Medical Device Class, if applicable:**   
**DUNS:**   
**Proprietary Name (If Applicable) and Established Name:**   
**Selling Unit NDC:**  **Unit of Use NDC:**  **UPC:**   
**UDI**  **CVX Code:**  **MXV Code:**   
**Description:**   
**Active Ingredient(s):**   
**URL for Additional Product Information:**   
**Address:**  **Address 2:**   
**City:**  **State:**  **Zip:**   
**Key Contact:**  **Email:**   
**Phone Number:**  **Fax:**   
**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:**   
**Number:**   
**Group E-mail:**   
**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... <input type="text" value="Direct-Ship Only"/>                               | Size:                           | <input type="text" value="60ct"/>  |
| if yes, enter class # <input type="text"/>  | Is the Product... <input type="text" value="Unit of Use"/>                                    | Strength:                       | <input type="text" value="1000mg"/>                                      |
| a product kit? <input type="text" value="No"/>  | Orphan Drug Status <input type="text"/>   | Dosage Form:                    | <input type="text" value="Oral Solid - Tablet"/>                         |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/>                         | FDA Approval Status <input type="text"/>  | Product Shape:                  | <input type="text" value="Oblong"/>                                      |
| co-licensed? <input type="text" value="No"/>  | Allergens Present <input type="text"/>  | Product Color:                  | <input type="text" value="Blue"/>  |
| latex-free? <input type="text" value="Yes"/>  | Country of Origin <input type="text" value="India"/>  | Product Imprint:                | <input type="text" value="R19' on one side and 'H' on the other side."/> |
| 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 | <input type="text" value="1 bottle of 60 tablets"/>             |
| <input type="checkbox"/> Box/Carton        | <input type="text" value="(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 |   |
| <input type="checkbox"/> Vial Powder Sgl   |   |
| <input type="checkbox"/> Vial Power Multi  |   |
| <input type="checkbox"/> Other: Write In   |   |

If Yes, how many of which package type?  
 Each  
 Inner/ Carton/Pack  
 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?   
 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:**   
**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: | 0.3         |                        | 2.125 | 3.875  | 0             | 1                 |
| Case:                         | 7.1         | 13.625                 | 9.5   | 5      |               | 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         | <input type="text" value="1"/>  |       | <input type="text" value="00331722669603"/> | <input type="text" value="20331722669607"/> |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                                 |       |   |   |
| <input checked="" type="checkbox"/> Case              | <input type="text" value="24"/> |       | <input type="text" value="20331722669607"/> |   |
| <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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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?  No  
 Does it 31722-669-60  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?  
 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**

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?  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  No  
 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

**ADD'L STORAGE INFORMATION**

Is the Product...  
 Controlled Substance?  No Controlled Substance Code   
 Controlled by State(s)?  No Listed Chemical (List I or II)  No  
 ARCOS Reportable?  No If yes, indicate which:   
 Schedule No.  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

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

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:**



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

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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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site on 31722-669-60 <input type="checkbox"/> Site Address: <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><b>Purchase order daily receipt cut off time by supplier</b></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>31722-669-60 <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></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 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><b>Overnight receipt available:</b> <input type="checkbox"/></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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: 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="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction:  |  |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>   |  |
| Other Data Information Required to Process PO:   | Return Instructions  |
| <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>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>   |
| Miscellaneous Notes:   |  |
| <input type="text"/>   |  |
| ADDITIONAL INFORMATION   |  |
| <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |  |