



# 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:**  **MVX 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?**

**e. Shelf life:**

Protect product (unit of sale) from light?

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="100ct"/>                  |
| if yes, enter class # <input type="text"/>   | Is the Product... <input type="text" value="Neither"/>                             | Strength:                       | <input type="text" value="40mg"/>                   |
| 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="Round"/>                  |
| co-licensed? <input type="text" value="No"/>   | Allergens Present <input type="text"/>   | Product Color:                  | <input type="text" value="Yellow"/>                 |
| latex-free? <input type="text" value="Yes"/>   | Country of Origin <input type="text" value="USA"/>                                 | Product Imprint:                | <input type="text" value="Upper: E6 Lower: Plain"/> |
| preservative-free? <input type="text" value="Yes"/>                                      | Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> |                                 |   |
| 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"/> |  |                                 |   |
| 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 100 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             |   |
| <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   |   |

Minimum order quantity?

If Yes, how many of which package type?

|                                 |                    |
|---------------------------------|--------------------|
| <input type="text" value="24"/> | Each               |
| <input type="text"/>            | Inner/ Carton/Pack |
| <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?**

**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 |               |                   |
| Item/Each:                    | 0.1         |                        | 1.5   | 3.5    | 0             | 1                 |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        | 0             |                   |
| Case:                         | 2.55        | 10                     | 7     | 4.5    | 0             | 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"/> | <input type="text" value="00331722180016"/> | <input type="text"/> |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | <input type="text"/>            | <input type="text"/> | <input type="text"/>                        | <input type="text"/> |
| <input checked="" type="checkbox"/> Case              | <input type="text" value="24"/> | <input type="text"/> | <input type="text" value="10331722180013"/> | <input type="text"/> |
| <input type="checkbox"/> Pallet                       | <input type="text"/>            | <input type="text"/> | <input type="text"/>                        | <input type="text"/> |

**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 the product label bear a CA Prop 65 warning?  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?

RQ Threshold:

Is this a marine pollutant?  No

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#

**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

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

**REMS:**

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:**

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?:

**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:**

