



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

Version 2021 Introduction Type:  0000 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?**   
 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? if yes, enter class # a product kit? | <input type="text" value="No"/>  | Is the Product... Direct-Ship Only                            | <input type="text" value=""/>  |
| if yes, list NDCs of component parts reverse numbered?               | <input type="text" value="No"/>  | Is the Product... Unit of Use                                 | <input type="text" value=""/>  |
| co-licensed?   | <input type="text" value="No"/>  | Orphan Drug Status  | <input type="text" value=""/>  |
| latex-free?  | <input type="text" value="Yes"/> | FDA Approval Status   | <input type="text" value=""/>  |
| preservative-free?   | <input type="text" value="Yes"/> | Allergens Present   | <input type="text" value="Dairy, Lactose, Casein"/>                                  |
| correctional institution block? opioid?                              | <input type="text" value="No"/>  | Country of Origin   | <input type="text" value="India"/>   |
| Cannabinoid?   | <input type="text" value="No"/>  | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/>  |
| If Unit Dose, is item bar coded to unit dose for hospital scanning?  | <input type="text" value=""/>    | Size:   | <input type="text" value="90 ct"/>   |
| If Unit Dose, indicate NDC here:                                     | <input type="text" value=""/>    | Strength:   | <input type="text" value="80 mg"/>   |
|  |                                  | Dosage Form:  | <input type="text" value="Film coated tablet"/>                                      |
|  |                                  | Product Shape:  | <input type="text" value="Oval, biconvex"/>  |
|  |                                  | Product Color:  | <input type="text" value="White to off-white"/>                                      |
|  |                                  | Product Imprint:  | <input type="text" value="Debossed with '80' on one side and 'A 56' on other side"/> |

**ORDER INFORMATION**

| Unit of Sale                               | What is the NDC selling unit?                                   |
|--|---|
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 90 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   | If Yes, how many of which package type?                         |
| <input type="checkbox"/> Vial Power Multi  | <input type="text" value="24"/> Each                            |
| <input type="checkbox"/> Other: Write In   | <input type="text" value="Inner/ Carton/ Pack"/>                |
|  | <input type="text" value="Case"/>                               |

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  Authorized Generic  \*If Authorized Generic, other section fields are not applicable  
 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: | 0.355       | 2.2                    | 2.2   | 4.75   | 22.99         | 1                 |
| Case:                         | 9.35        | 13.6                   | 9.4   | 5.75   | 735.08        | 24                |
| Pallet:                       |             |                        |       |        |               |                   |

**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="00331722427906"/> | <input type="text" value="00331722427906"/> |
| <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="20331722427900"/> | <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:



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

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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)

- 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)

- 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:

- Passenger  No
- 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  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

| SDS Hazard Classification   |   |
|---|---|
| <input checked="" type="checkbox"/> Organic   | <input type="checkbox"/> Corrosive      |
| <input type="checkbox"/> Inorganic  | <input type="checkbox"/> Oxidizer       |
| <input type="checkbox"/> Steroid/Androgen   | <input type="checkbox"/> Contact Hazard |
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> | <input type="checkbox"/> No             |
| NFPA Storage Level: <input type="text"/>  |   |
| Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/>               | <input type="checkbox"/> No             |

| Hazardous Waste Identification                 |   |
|--|---|
| EPA Hazardous Waste Code: <input type="text"/> | Waste Characteristics: <input type="text"/> |

| REMS or REGISTRY RESTRICTIONS  |                              |
|--|------------------------------|
| Is there a REMS on this product? <input type="checkbox"/> No <input type="checkbox"/> Yes                |                              |
| If Yes, is it managed with a pharmacy registry? <input type="checkbox"/> No <input type="checkbox"/> Yes |                              |
| Website URL: <input type="text"/>  |                              |
| Med Guide Required <input type="checkbox"/> No <input type="checkbox"/> Yes                              |                              |
| Limited Distribution Requirement <input type="checkbox"/> No <input type="checkbox"/> Yes                |                              |
| Comments / Details: (For example, iPledge program?) <input type="text"/>                                 |                              |
| <b>REMS:</b>   |                              |
| REMS Program Manager Name: <input type="text"/>  | Phone: <input type="text"/>  |
| Supplier Manages REMS registry exclusively: <input type="checkbox"/> No <input type="checkbox"/> Yes     |                              |
| Wholesale distributor support: <input type="text"/>  |                              |
| Provider Name: <input type="text"/>  | DEA #: <input type="text"/>  |
| Site Enrollment Number assigned by Supplier: <input type="text"/>  | NCPDP#: <input type="text"/> |
|  | NPI #: <input type="text"/>  |
| Comments <input type="text"/>  |                              |
| <b>Registry:</b>   |                              |
| Registry Program Contact Name: <input type="text"/>  | Phone: <input type="text"/>  |
| Comments <input type="text"/>  |                              |

| RETURN INSTRUCTIONS  |  |
|--|--|
| Contact tel. # if product received damaged: <input type="text"/>   | 1-866-827-3647                             |
| Is product returnable for credit: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes                                    |  |
| URL/Link to returns policy: <input type="text"/>   | contact - customerservice@camberpharma.com |
| Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No <input type="checkbox"/> Yes |  |
| If so, which states? Other requirements? Comments? <input type="text"/>  |  |

### 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"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/><br/>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>Ships same day for next day receipt: <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<br/> <input type="checkbox"/> Tuesday<br/> <input type="checkbox"/> Wednesday<br/> <input type="checkbox"/> Thursday<br/> <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"/><br/> Fax: <input type="text"/> Fax #: <input type="text"/><br/> 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:  | ADDITIONAL INFORMATION   |
| <p><input type="text"/></p>   | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |