



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

Version 2021 Introduction Type:   Final Version Date:

## PRODUCT INFORMATION

**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:**

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**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:**

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?

If yes, enter class # a product kit?

If yes, list NDCs of component parts reverse numbered?

co-licensed?

latex-free?

preservative-free?

correctional institution block?

opioid?

Cannabinoid?

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Neither**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin**

Is this product covered under the Trade Agreements Act (TAA)?

**Size:**

**Strength:**

**Dosage Form:**

**Product Shape:**

**Product Color:**

**Product Imprint:**

## ORDER INFORMATION

**Unit of Sale**

<input checked="" type="checkbox"/>	x	Bottle
<input type="checkbox"/>		Box/Carton
<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

**What is the NDC selling unit?**   
(Write-in, e.g. 1 Box of 10 Vials)

**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?**

(Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

<input type="text"/>	Each
<input type="text"/>	Gram
<input type="text"/>	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		1.625	3	0	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2.55	10.5	7.25	4.5		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	1		00331722179010	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722179017	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)**

As of date:

**WHOLESALE USE ONLY:**

**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)

- 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  No
- Passenger & Cargo  No

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?

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

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  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  Yes  
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  Yes  
If Yes, is it managed with a pharmacy registry?  No  Yes  
Website URL:

Med Guide Required  No  Yes  
Limited Distribution Requirement  No  Yes  
Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  Yes  
Wholesale distributor support:  No  Yes  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

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:  No  Yes

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> <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 only <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>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</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: <input type="text"/></p> <p>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:	
<p><input type="text"/></p>	
	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>