



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

Version 2024 Introduction Type:  0000 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:  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:

## 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)?

## PRODUCT DESCRIPTION INFORMATION

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 Powder 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?

Rx billing unit to pharmacy:

<input type="text"/>	Each
<input type="text"/>	Gram
<input type="text"/>	Milliliter

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

HCPCS J-Code:

## 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:	0.24	2.18	2.18	3.87	18.39	1
Box/Carton/Bundle/Inner Pack:						
Case:	6.6	13.75	9.25	5	635.94	24
Pallet:						

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1		00331722021012	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case		24		20331722021016	
<input type="checkbox"/> Pallet					

## COST INFORMATION

Regular Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:



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Version 2024

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

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
NFPA Storage Level:

Is the product a NIOSH hazardous drug?  Yes  
If yes, indicate which:  Group 2 items (non-antineoplastic that meets a hazard criterion)

### 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

### 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:



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Version 2024

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"/></li><li>c. Fax <input type="checkbox"/></li><li>d. Phone only <input type="checkbox"/></li><li>e. Supplier Web Site only <input type="checkbox"/></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 #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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> <ul style="list-style-type: none"><li><input type="checkbox"/> Monday</li><li><input type="checkbox"/> Tuesday</li><li><input type="checkbox"/> Wednesday</li><li><input type="checkbox"/> Thursday</li><li><input type="checkbox"/> Friday</li></ul> <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:	ADDITIONAL INFORMATION
<input type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>