



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 7/22/2024

## 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?  No

Is this product to be shipped to customers on dry ice?  No

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?  \*Yes  No

d. Store product (unit of sale) upright?  No

Protect product (unit of sale) from light?  No

e. Shelf life:  
Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is?  
a legend device?  No  
if yes, enter class #

a product kit?  No  
if yes, list NDCs of component parts reverse numbered?  No

co-licensed?  No  
latex-free?  Yes  
preservative-free?  Yes  
correctional institution block?  No  
opioid?  No  
Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes  
If Unit Dose, indicate NDC here:

Is the Product...  Direct-Ship Only  
Is the Product...  Unit Dose  
Orphan Drug Status:

FDA Approval Status:

Allergens Present:

Country of Origin:

Is this product covered under the Trade Agreements Act (TAA)?  No

## PRODUCT DESCRIPTION INFORMATION

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

## 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?:

## ORDER INFORMATION

Unit of Sale:  Bottle,  Box/Carton,  Ampule,  Glass Tube,  Vial Liquid Sgl,  Vial Liquid Multi,  Vial Powder Sgl,  Vial Powder Multi,  Other: Write In

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

Minimum order quantity?  Yes

If Yes, how many of which package type?  
 Each,  Inner/Carton/Pack,  Case

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No

Is product exempt from DSCSA?  No

If yes, select exemption:  
Other exemption - Write in:

Is product repackaged?  No

Is product sold by manufacturer's exclusive distributor?  Yes  No

Has FDA granted waiver/exception/exemption for product?  No

If yes, attach documentation from FDA.

GLN:

GCP:

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product:

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

Rx billing unit to pharmacy:  
 Each,  Gram,  Milliliter

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

## 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="00331722203319"/>	<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="20"/>	<input type="text"/>	<input type="text" value="20331722203313"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.66	6.32	2.53	2.77	44.29	1
Case:	13.66	13.04	8.3	5.93	641.82	20
Pallet:						

## COST INFORMATION

Regular Cost:

Invoice Cost (WAC) (\$):

As of date:

WHOLESALE USE ONLY:  
Vendor #:   
Whsl. Code #:   
Fineline Code:

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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
- 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?  Yes  No  Controlled Substance Code
- Controlled by State(s)?  Yes  No  Listed Chemical (List I or II)  No
- ARCOS Reportable?  Yes  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  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:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

\*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

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" value="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" value="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"/>	

