



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

Version 2021

Introduction Type:  Post Launch Change

1 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... Unit of Use

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?

(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		
Box/Carton/Bundle/Inner Pack:						
Case:	3.65	11.5	8	4.5	414	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	1		00331722015905	00331722015905
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722015909	
<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)  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?  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 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?:  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?  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?  No  
 Website URL:

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

**REMS:**  No

REMS Program Manager Name:       Phone:

Supplier Manages REMS registry exclusively:  No

Wholesale distributor support:  No

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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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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>