



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

Version 2024 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION**

Company Name:  Application:   
 Application Number for NDA/ANDA/BLA; PMA/510(k):  NDA 505(b) Type:   
 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		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	Size: <input type="text" value="30 ct"/>
a legend device?	<input type="text" value="No"/>	Is the Product... Neither	Strength: <input type="text" value="800 mg"/>
if yes, enter class #		Orphan Drug Status	Dosage Form: <input type="text" value="Tablet"/>
a product kit?	<input type="text" value="No"/>	FDA Approval Status	Product Shape: <input type="text" value="Oval"/>
if yes, list NDCs of component parts		Allergens Present	Product Color: <input type="text" value="Beige"/>
reverse numbered?	<input type="text" value="No"/>	Country of Origin	Product Imprint: <input type="text" value="'1217'"/>
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	
latex-free?	<input type="text" value="Yes"/>		
preservative-free?	<input type="text" value="Yes"/>		
correctional institution block?	<input type="text" value="No"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		

**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?

If Yes, how many of which package type?  
 Each,  Inner/Carton/Pack,  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)  
 HCPCS J-Code:

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:	0.18	1.79	1.79	3.21		1
Case:	5.464	10.63	7.13	4.81		24
Pallet:	782.685	47.24	39.37	47.24		3,360

**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	Y	1		00372578148065	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	Y	24		40372578148063	
<input checked="" type="checkbox"/> Case	Y	3,360		50372578148060	
<input checked="" type="checkbox"/> Pallet	Y				

**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?

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?

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  NoRQ 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  Controlled Substance Code
- Controlled by State(s)?  No  Listed Chemical (List I or II)
- ARCOS Reportable?  No  If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?:

**CLASS OF TRADE RESTRICTION:**

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- 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?

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?

Website URL:

Med Guide Required  No

Limited Distribution Requirement  No

Comments / Details: (For example, iPledge program?)

**REMS:**

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:**

Registry Program Contact Name:  Phone:

Comments

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:  888-304-5022

Is product returnable for credit:  Yes

URL/Link to returns policy:  [www.vionausa.com](http://www.vionausa.com)

Special regulations or return requirements for this product in certain states?

If so, which states? Other requirements? Comments?

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

