



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

Version 2020

Introduction Type:

Final Version

Date:

### PRODUCT INFORMATION

Company Name:  Application:   
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):   
 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 a legend device? <input type="text" value="No"/>	Is the Product... Direct-Ship Only <input type="text" value="Neither"/>	Size: <input type="text" value="500 ct"/>
if yes, enter class # <input type="text"/>	Is the Product... Orphan Drug Status <input type="text"/>	Strength: <input type="text" value="10 mg/6.25 mg"/>
if yes, list NDCs of component parts <input type="text"/>	FDA Approval Status <input type="text"/>	Dosage Form: <input type="text" value="Tablet"/>
reverse numbered? <input type="text" value="No"/>	Allergens Present <input type="text"/>	Product Shape: <input type="text" value="Round"/>
co-licensed? <input type="text" value="No"/>	Country of Origin <input type="text" value="India"/>	Product Color: <input type="text" value="White to Off-white"/>
latex-free? <input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>	Product Imprint: <input type="text" value="115"/>
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	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 500 Tablets"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="12"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/Cartron/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> 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? <input type="text" value="1 Bottle"/>	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

### DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  GLN:   
 Is product exempt from DSCSA?   
 If yes, select exemption:   
 Other exemption - Write in:   
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?  If Yes, was original product purchased direct from mfr?   
 Has FDA granted waiver/exception/exemption for product?  If yes, attach documentation from FDA.

### ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.28	1.9	1.9	3.8		1
Box/Cartron/Bundle/Inner Pack:						
Case:	4.36	7.87	5.98	4.8		12
Pallet:	962.96	47.24	39.37	47.24		2,604

### GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00372578115050	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40372578115058	
<input checked="" type="checkbox"/> Pallet	2,604		50372578115055	

### COST INFORMATION

### WHOLESALE USE ONLY:

Regular Cost <input type="text"/>	Vendor #: <input type="text"/>
Invoice Cost (WAC) (\$) <input type="text"/>	Whsl. Code #: <input type="text"/>
As of date: <input type="text"/>	Fineline Code: <input type="text"/>

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

\*Please provide any additional information on page 2.

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?  No
  - 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?  No  
(If yes, attach SDS with special instructions.)
- 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 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?:  No

### 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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify 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:       PCPDP#:
- 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 returns requirements for this product in certain states?
- If so, which states? Other requirements? Comments?

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

