



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

Version 2021 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

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:

**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? if yes, enter class # a product kit?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value=""/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value=""/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Lactose, Dairy, Dye, Corn, Alcohol, Animal, Rennet, Casein, Whey"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="USA"/>
correctional institution block? opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
Cannabinoid?	<input type="text" value="No"/>	Size:	<input type="text" value="100 ct"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>	Strength:	<input type="text" value="10 mg"/>
If Unit Dose, indicate NDC here:	<input type="text" value=""/>	Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="Round, flat"/>
		Product Color:	<input type="text" value="Pink"/>
		Product Imprint:	<input type="text" value="Debossed with 'T 278' on one side and plain on the other side"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 100 Tablets"/>
<input type="checkbox"/> Box/Carton	<input type="text" value=""/>
<input type="checkbox"/> Ampule	<input type="text" value=""/>
<input type="checkbox"/> Glass	<input type="text" value=""/>
<input type="checkbox"/> Tube	<input type="text" value=""/>
<input type="checkbox"/> Vial Liquid Sgl	<input type="text" value=""/>
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value=""/>
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/>
<input type="checkbox"/> Vial Powder Multi	<input type="text" value=""/>
<input type="checkbox"/> Other: Write In	<input type="text" value=""/>

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)  
 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:	0.09	1.56	1.56	2.94	7.16	1
Case:	2.2	10.8	7	3.2	241.92	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	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722930017"/>	<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="24"/>	<input type="text"/>	<input type="text" value="10331722930014"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
 Is the product a CA Prop 65 carcinogen?   
 Is the product a CA Prop 65 reproductive toxicant?   
 Does the product label bear a CA Prop 65 warning?

c. Contact Hazard?

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

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?   
 RQ Threshold:

Is this a marine pollutant?

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#

### SDS Hazard Classification

Organic  
 Inorganic  
 Steroid/Androgen

Corrosive  
 Oxidizer  
 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?   
 If Yes, is it managed with a pharmacy registry?   
 Website URL: <https://opioidanalgesicrems.com/home.html>

Med Guide Required   
 Limited Distribution Requirement   
 Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name: Prathima Arrabelly Phone: (631) 881-4614 Ext. 1412  
 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

### ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?  Controlled Substance Code: 9652

Controlled by State(s)?  Listed Chemical (List I or II)

ARCOS Reportable?  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:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit:   
 URL/Link to returns policy:

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

If so, which states? Other requirements? Comments?

DEA Form 222 or its electronic equivalent is required for all returns in all states.

### 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.

