



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

Version 2020 Introduction Type:  Post Launch Change  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?

e. Shelf life: Protect product (unit of sale) from light?   
 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"/>	Size:	<input type="text" value="1 x 50mL multiple-dose vial"/>
if yes, enter class # <input type="text"/>	Is the Product... Orphan Drug Status <input type="text"/>	Strength:	<input type="text" value="2.5GM/50ML (50MG/ML)"/>
a product kit? <input type="text" value="No"/>	FDA Approval Status <input type="text"/>	Dosage Form:	<input type="text" value="INJECTABLE"/>
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	Allergens Present <input type="text" value="Container closure is not made with natural rubber latex."/>	Product Shape:	<input type="text"/>
co-licensed? <input type="text" value="No"/>	Country of Origin <input type="text" value="India"/>	Product Color:	<input type="text"/>
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"/>
preservative-free? <input type="text" value="Yes"/>			
correctional institution block? <input type="text" value="Yes"/>			
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 type="checkbox"/> Bottle	<input type="text" value="1 Box containing 1 Vial"/>
<input checked="" 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="40"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 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?  GLN:   
 Is product exempt from DSCSA?   
 If yes, select exemption:  
 Other exemption - Write in:   
 Is product repackaged?  If Yes, was original product purchased direct from mfr?   
 Is product sold by manufacturer's exclusive distributor?   
 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		
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	11.464	10.433	8.465	6.89	608.49273	40
Pallet:					0	

**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		00370700188224	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	40		20370700188228	
<input type="checkbox"/> Pallet				

**COST INFORMATION**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:

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

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

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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?  Yes  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:

Passenger  
 Cargo  
 Passenger & Cargo

Is this a reportable quantity?  Yes  
 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  Yes  Controlled Substance Code

Controlled by State(s)?  No  Yes  Listed Chemical (List I or II)  No

ARCOS Reportable?  No  Yes  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:

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

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
 If yes, indicate which:  Yes  No  
 Group 1 items (antineoplastic)

**Hazardous Waste Identification**

EPA Hazardous Waste Code:  Waste Characteristics

**REMS or REGISTRY RESTRICTIONS**

Is there a REMS on this product?  No  Yes

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:

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?

**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	
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"/>

Standard Order Receipt and Processing	
<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:	
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"/>

Overnight and Priority Overnight PO Processing	
<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:	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:	
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"/>

Return Instructions	
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:
<input type="text"/>

ADDITIONAL INFORMATION	
Is product order for scheduled patient procedure?	<input type="checkbox"/>
Is product order for restocking purposes?	<input type="checkbox"/>