



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

Version 2020

Introduction Type:  New Item

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 And Drop-Ship <input type="text" value="Neither"/>	Size: <input type="text" value="30 ct bottle"/>	
if yes, enter class # <input type="text"/>	Is the Product... Orphan Drug Status <input type="text"/>	Strength: <input type="text" value="10mg"/>	
a product kit? <input type="text" value="No"/>	FDA Approval Status <input type="text"/>	Dosage Form: <input type="text" value="Tablet"/>	
if yes, list NDCs of component parts <input type="text"/>	Allergens Present <input type="text" value="See Package Insert - patient specific"/>	Product Shape: <input type="text" value="Round, biconvex"/>	
reverse numbered? <input type="text" value="No"/>	Country of Origin <input type="text" value="India"/>	Product Color: <input type="text" value="white to off white"/>	
co-licensed? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>	Product Imprint: <input type="text" value="debossed 'C52' one side; plain on other"/>	
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 Power 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)

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?  If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.066	1.575	1.575	3.031	7.519065	1
Box/Carton/Bundle/Inner Pack:	2.923	11.02	7.4	4.33	353.10284	24
Case:	11.69	16.54	12.60	10.24	2132.4137	96
Pallet:	393.81	47.24	39.37	47.24	87875.896	3072

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		00372241034220	<input type="text" value="NOS"/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		20372241034224	
<input checked="" type="checkbox"/> Case	96		40372241034228	
<input checked="" type="checkbox"/> Pallet	3072		50372241034225	

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

Wholesaler Use Only:  
 Vendor #:   
 Whsl. Code #:   
 Fineline Code:

\*Please provide any additional information on page 2.

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

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											
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <span style="float: right;">No</span></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <span style="float: right;">No</span>            Is the product a CA Prop 65 reproductive toxicant? <span style="float: right;">No</span>            Does the product label bear a CA Prop 65 warning? <span style="float: right;">No</span></p> <p>c. Contact Hazard? <span style="float: right;">No</span></p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <span style="float: right;">No</span></p> <p>e. Does the product contain DEHP? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is the product restricted for air shipment? If so, indicate restriction:  <input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <span style="float: right;">No</span>            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <span style="float: right;">No</span></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?            No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;"><input type="checkbox"/> Organic</td> <td style="border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/> </td> </tr> </table> <p style="margin-top: 5px;">Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>            If yes, indicate which: <input style="width: 100%;" type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">Hazardous Waste Identification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none; padding: 2px;">EPA Hazardous Waste Code: <input style="width: 150px;" type="text"/></td> <td style="border: none; padding: 2px;">Waste Characteristics <input style="width: 100px;" type="text"/></td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <span style="float: right;">No</span></p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <span style="float: right;">No</span></p> <p>Limited Distribution Requirement <span style="float: right;">No</span></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b> <span style="float: right;">No</span></p> <p>REMS Program Manager Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 100px;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 100%;" type="text"/></p> <p>Provider Name: <input style="width: 150px;" type="text"/> DEA #: <input style="width: 100px;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 150px;" type="text"/> PCPDP#: <input style="width: 100px;" type="text"/></p> <p>NPI #: <input style="width: 100px;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b> <span style="float: right;">No</span></p> <p>Registry Program Contact Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 100px;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard	<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 150px;" type="text"/>	Waste Characteristics <input style="width: 100px;" type="text"/>
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ADD'L STORAGE INFORMATION											
<p>Is the Product...</p> <p>Controlled Substance? <span style="float: right;">No</span> Controlled Substance Code <input style="width: 100px;" type="text"/></p> <p>Controlled by State(s)? <span style="float: right;">No</span> Listed Chemical (List I or II) <span style="float: right;">No</span></p> <p>ARCOS Reportable? <span style="float: right;">No</span> If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input style="width: 100px;" type="text"/> Is it a scheduled listed chemical product?: <span style="float: right;">No</span></p>											
CLASS OF TRADE RESTRICTION:											
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">Yes</span></p> <p>Restricted to retail pharmacy only: <span style="float: right;">No</span></p> <p>Restricted to hospital, clinics, and physician offices only: <span style="float: right;">No</span></p> <p>Restricted from US territories? (explain in comments) <span style="float: right;">No</span></p> <p>Comments: <input style="width: 100%;" type="text"/></p>											
RETURN INSTRUCTIONS											
<p>Contact tel. # if product received damaged: <input style="width: 100px;" type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: <span style="float: right;">Yes</span></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <span style="float: right;">No</span></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>											
MISCELLANEOUS NOTES and/or Image of Product Barcode:											
<input style="width: 100%; height: 100%;" type="text"/>											

