



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: Months

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... <input type="text"/>	Direct-Ship Only <input type="text"/>	Size: <input type="text"/>
if yes, enter class # <input type="text"/>	Is the Product... <input type="text"/>	Neither <input type="text"/>	
if yes, list NDCs of component parts <input type="text"/>	Orphan Drug Status <input type="text"/>	FDA Approval Status <input type="text"/>	Strength: <input type="text" value="EQ 50mg Base/Vial"/>
reverse numbered? <input type="text" value="No"/>	Allergens Present <input type="text" value="The vial stopper is not made with natural rubber latex."/>	Country of Origin <input type="text" value="Switzerland"/>	Dosage Form: <input type="text" value="Injectable"/>
co-licensed? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>		Product Shape: <input type="text"/>
latex-free? <input type="text" value="Yes"/>			Product Color: <input type="text"/>
preservative-free? <input type="text" value="Yes"/>			Product Imprint: <input type="text"/>
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

<input type="checkbox"/>	Bottle
<input checked="" type="checkbox"/>	Box/ Carton
<input type="checkbox"/>	Ampule
<input type="checkbox"/>	Glass
<input type="checkbox"/>	Tube
<input type="checkbox"/>	Vial Liquid Sgl
<input type="checkbox"/>	Vial Liquid Multi
<input type="checkbox"/>	Vial Powder Sgl
<input type="checkbox"/>	Vial Power Multi
<input type="checkbox"/>	Other: Write In

What is the NDC selling unit?

Minimum order quantity?

If Yes, how many of which package type?

<input type="text" value="10"/>	Each
<input type="text"/>	Inner/ Carton/ Pack
<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?

Rx billing unit to pharmacy:

<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?

Is product exempt from DSCSA?

GLN:

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, was original product purchased direct from mfr?

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:	0.12	2.16	1.57	3.15	10.68228	1
Case:	1.2	12	4	4.5	216	10
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		00370700278970	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	10		40370700278978	
<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.

*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															
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? Yes <input type="checkbox"/></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No <input type="checkbox"/> Is the product a CA Prop 65 reproductive toxicant? No <input type="checkbox"/> Does the product label bear a CA Prop 65 warning? No <input type="checkbox"/></p> <p>c. Contact Hazard? No <input type="checkbox"/></p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No <input type="checkbox"/></p> <p>e. Does the product contain DEHP? No <input type="checkbox"/></p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No <input type="checkbox"/></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No <input type="checkbox"/></p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No <input type="checkbox"/></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No <input type="checkbox"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No <input type="checkbox"/> RQ Threshold: <input style="width: 50%;" type="text"/></p> <p>Is this a marine pollutant? No <input type="checkbox"/></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? No <input type="checkbox"/> (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 style="width: 50%;" type="text"/></p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: 1px solid black; padding: 5px;"> <tr> <td><input type="checkbox"/> Organic</td> <td><input type="checkbox"/> Corrosive</td> </tr> <tr> <td><input type="checkbox"/> Inorganic</td> <td><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td><input type="checkbox"/> Steroid/Androgen</td> <td><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/></td> </tr> <tr> <td colspan="2">Is the product a NIOSH hazardous drug? Yes <input type="checkbox"/></td> </tr> <tr> <td colspan="2">If yes, indicate which: Group 1 items (antineoplastic) <input style="width: 50%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black; padding: 5px;"> <tr> <td>EPA Hazardous Waste Code: <input style="width: 50%;" type="text"/></td> <td>Waste Characteristics <input style="width: 50%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No <input type="checkbox"/></p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 50%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required No <input type="checkbox"/></p> <p>Limited Distribution Requirement No <input type="checkbox"/></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 50%;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 50%;" type="text"/></p> <p>Provider Name: <input style="width: 50%;" type="text"/> DEA #: <input style="width: 20%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 50%;" type="text"/> PCPDP#: <input style="width: 20%;" type="text"/></p> <p>NPI #: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <p>Registry Program Contact Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50%;" type="text"/></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? <input style="width: 50%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>	<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: 50%;" type="text"/>		Is the product a NIOSH hazardous drug? Yes <input type="checkbox"/>		If yes, indicate which: Group 1 items (antineoplastic) <input style="width: 50%;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 50%;" type="text"/>	Waste Characteristics <input style="width: 50%;" type="text"/>
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ADD'L STORAGE INFORMATION															
<p>Is the Product...</p> <p>Controlled Substance? No <input type="checkbox"/> Controlled Substance Code <input style="width: 50%;" type="text"/></p> <p>Controlled by State(s)? No <input type="checkbox"/> Listed Chemical (List I or II) No <input type="checkbox"/></p> <p>ARCOS Reportable? No <input type="checkbox"/> If yes, indicate which: <input style="width: 50%;" type="text"/></p> <p>Schedule No. <input style="width: 50%;" type="text"/> Is it a scheduled listed chemical product?: No <input type="checkbox"/></p>															
CLASS OF TRADE RESTRICTION:															
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>															
MISCELLANEOUS NOTES and/or Image of Product Barcode:															

