



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

Version 2020

Introduction Type: Open Stock

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? if yes, enter class # a product kit?	<input type="text" value="No"/>	Is the Product... Is the Product... Orphan Drug Status	<input type="text" value="Direct-Ship Only"/> <input type="text" value="Neither"/>
if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="Yes"/> <input type="text" value="Yes"/> <input type="text" value="No"/> <input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="text"/> <input type="text"/>	Allergens Present	<input type="text" value="Not made with natural rubber latex."/>
		Country of Origin	<input type="text" value="Spain"/>
		Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
		Size:	<input type="text" value="30gm"/>
		Strength:	<input type="text" value="0.05%"/>
		Dosage Form:	<input type="text" value="Topical"/>
		Product Shape:	<input type="text"/>
		Product Color:	<input type="text"/>
		Product Imprint:	<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?

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?

<input type="text" value="48"/>	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

(Write-in, e.g. 1 Vial)

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?

GLN:

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:	0.13	1.85	1.299	7.126	17.124847	1
Case:	5.6	12.598	7.165	6.378	575.70807	48
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		00370700106167	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700106164	
<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? No</p> <p>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</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</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</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No</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</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 RQ Threshold: <input style="width: 50%;" type="text"/></p> <p>Is this a marine pollutant? No</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 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: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; 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 checked="" type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: none;"><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/></td> </tr> <tr> <td colspan="2" style="border: none;">Is the product a NIOSH hazardous drug? No</td> </tr> <tr> <td colspan="2" style="border: none;">If yes, indicate which: <input style="width: 100%;" 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: none;"> <tr> <td style="width: 60%; border: none;">EPA Hazardous Waste Code: <input style="width: 90%;" type="text"/></td> <td style="width: 40%; border: none;">Waste Characteristics <input style="width: 90%;" 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</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">REMS Program Manager Name: <input style="width: 90%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td colspan="2">Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td colspan="2">Wholesale distributor support: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Provider Name: <input style="width: 90%;" type="text"/></td> <td>DEA #: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 90%;" type="text"/></td> <td>PCPDP#: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td></td> <td>NPI #: <input style="width: 90%;" type="text"/></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Registry Program Contact Name: <input style="width: 90%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 90%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input checked="" 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? 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<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes</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%; height: 30px;" type="text"/></p>																															
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