



# 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?

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" value="15 grams"/>
if yes, enter class # <input type="text"/>	Is the Product... <input type="text"/>	Neither <input type="text"/>	Strength: <input type="text" value="0.05%"/>
if yes, list NDCs of product kit? <input type="text"/>	Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="OINTMENT"/>
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>		Product Shape: <input type="text"/>
co-licensed? <input type="text" value="No"/>	Allergens Present <input type="text" value="Not made with natural rubber latex."/>		Product Color: <input type="text"/>
latex-free? <input type="text" value="No"/>	Country of Origin <input type="text" value="Spain"/>		Product Imprint: <input type="text"/>
preservative-free? <input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)? <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

<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:  Each

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

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?

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:	0.033	1.457	4.528	1.083	7.1448716	1
Case:	3.5	12.6	7.5	5.1	481.95	48
Pallet:					0	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700146156	
Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700146153	
<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:

Version 2020

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 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? <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 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? <span style="float: right;">No</span></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 &amp; Cargo</p> <p>Is this a reportable quantity? <span style="float: right;">No</span>            RQ Threshold: <input style="width: 50%;" 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 style="width: 50%;" 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="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 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: 100%;" type="text"/> </td> </tr> <tr> <td colspan="2" style="border: none; padding-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"/> </td> </tr> </table> </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="width: 60%; border: none;">EPA Hazardous Waste Code: <input style="width: 95%;" type="text"/></td> <td style="width: 40%; border: none;">Waste Characteristics <input style="width: 95%;" type="text"/></td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 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?            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></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">REMS Program Manager Name: <input style="width: 95%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 95%;" 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: 95%;" type="text"/></td> <td>DEA #: <input style="width: 95%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 95%;" type="text"/></td> <td>PCPDP#: <input style="width: 95%;" type="text"/></td> </tr> <tr> <td></td> <td>NPI #: <input style="width: 95%;" type="text"/></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Registry Program Contact Name: <input style="width: 95%;" type="text"/></td> <td style="width: 40%;">Phone: <input style="width: 95%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table> </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: 100%;" type="text"/>		Is the product a NIOSH hazardous drug? <span style="float: right;">No</span> If yes, indicate which: <input style="width: 100%;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 95%;" type="text"/>	Waste Characteristics <input style="width: 95%;" type="text"/>	REMS Program Manager Name: <input style="width: 95%;" type="text"/>	Phone: <input style="width: 95%;" type="text"/>	Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/>		Wholesale distributor support: <input style="width: 100%;" type="text"/>		Provider Name: <input style="width: 95%;" type="text"/>	DEA #: <input style="width: 95%;" type="text"/>	Site Enrollment Number assigned by Supplier: <input style="width: 95%;" type="text"/>	PCPDP#: <input style="width: 95%;" type="text"/>		NPI #: <input style="width: 95%;" type="text"/>	Registry Program Contact Name: <input style="width: 95%;" type="text"/>	Phone: <input style="width: 95%;" type="text"/>	Comments <input style="width: 100%;" 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: 100%;" 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: 100%;" 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: <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>																													
RETURN INSTRUCTIONS																													
<p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 100%;" 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: 100%;" type="text"/></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"/>																													



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

Version 2020

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product		Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> <input type="checkbox"/> b. Autofax <input type="checkbox"/> <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>		<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:		Overnight and Priority Overnight PO Processing	
Expedited freight fees billed with each order: <input type="checkbox"/> Drop Ship service fee billed with each order: <input type="checkbox"/> Drop Ship miscellaneous fees billed: <input type="checkbox"/> Comments: <input type="text"/>		<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="checkbox"/> 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:		Return Instructions	
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"/>		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:		ADDITIONAL INFORMATION	
<input type="text"/>		Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>	