



# 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="30 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:	0.066	1.457	6.142	1.083	9.6916522	1
Case:	5.35	12.8	7.2	6.7	617.472	48
Pallet:					0	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700146163	
Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700146160	
<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

Is this product (check all that apply):

- a. Cytotoxic?  No
  - b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
    - 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?  No  
(If yes, attach SDS with special instructions.)
  - e. Does the product contain DEHP?  No
- Is this product regulated for shipment by DOT?  No  
(if yes, answer a-e below and provide SDS)

- 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?  No  
(if yes, answer a-e below and provide SDS)
- 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?  No

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 Controlled Substance Code
- Controlled by State(s)?  No Listed Chemical (List I or II)  No
- ARCOS Reportable?  No 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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug?  No
- If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
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:

Order Method for Designated Drop Ship Product	
Purchase orders may be accepted by:	
a. EDI <input type="checkbox"/>	<input type="text"/>
b. Autofax <input type="checkbox"/>	<input type="text"/>
c. Fax <input type="checkbox"/>	Fax Number: <input type="text"/>
d. Phone only <input type="checkbox"/>	Fax Number: <input type="text"/>
e. Supplier Web Site only <input type="checkbox"/>	Phone No.: <input type="text"/>
	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"/>

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="text"/>
Ships for second day receipt:	<input type="text"/>
Ships regular ground for 3-10 days receipt:	<input type="text"/>

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:	<div style="border: 1px solid black; min-height: 50px;"></div>

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="text"/>
Other fees apply:	<input type="text"/>

Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="text"/>
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<div style="border: 1px solid black; min-height: 50px;"></div>

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="text"/>
URL/Link to returns policy:	<input type="text"/>
Special regulations or returns requirements for this product in certain states?	<input type="text"/>
If so, which states? Other requirements? Comments?	
<div style="border: 1px solid black; min-height: 50px;"></div>	

Miscellaneous Notes:	
<div style="border: 1px solid black; min-height: 100px;"></div>	

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