



# 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? 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 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="60 grams"/>
		Strength:	<input type="text" value="0.05%"/>
		Dosage Form:	<input type="text" value="OINTMENT"/>
		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 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="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

## 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?

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:	0.13	1.85	7.126	1.299	17.124847	1
Case:	9.5	15.8	8.4	7.9	1048.488	48
Pallet:					0	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700146170	
Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700146177	
<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 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"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <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"/>