



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date: 07.02.2020

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: Individual Unit 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):
 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:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 co-licensed?
 Is the Product... Direct-Ship Only
 Is the Product... Neither
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate NDC here:
 Country of Origin:
 Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size:
 Strength:
 Dosage Form:
 Product Shape:
 Product Color:
 Product Imprint:

ORDER INFORMATION

Unit of Sale: Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 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?
 Each
 Inner/Carton/Pack
 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?
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
 Each
 Gram
 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? If Yes, was original product purchased direct from mfr?
 Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.
 Has FDA granted waiver/exception/exemption for product?

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.2283	0.056	0.124	0.056	0.00038886	1
Box/Carton/Bundle/Inner Pack:	3.0696	9.173	4.96	6.929	315.256196	12
Case:	24.5568	19.094	10.826	15.354	3173.85058	96
Pallet:	486.1144	47.991	37.708	40	72385.7851	1728
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	2D		
<input type="text" value="Yes"/>	<input type="text"/>	<input type="text"/>	Item	<input checked="" type="checkbox"/>	1	00364380891062
			Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	12	20364380891066
			Case	<input checked="" type="checkbox"/>	96	50364380891067
			Pallet	<input checked="" type="checkbox"/>	1728	70364380891061
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		
				<input type="checkbox"/>		

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 Federal Excise Tax Per Unit of Sale
 As of date:

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fine Line Code: