



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

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: 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: Months
 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? Yes No

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:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.02	1.61	2.98	1.61	7.724458	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	3.13	9.7	3.81	6.49	239.85093	24
Pallet:	638.14	48	48	40	92160	4752
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Item	Saleable Unit		
<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00368382899064
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input checked="" type="checkbox"/>	<input type="checkbox"/>	24	40368382899062
			<input checked="" type="checkbox"/>	<input type="checkbox"/>		50368382899069
			<input type="checkbox"/>	<input type="checkbox"/>		
			<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 #:

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: