



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

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  Controlled Room – between 20 and 25 C (68° – 77° F)

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...  
 Unit of Use

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

<input checked="" type="checkbox"/>	Bottle
<input 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 Powder 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"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text" value="1"/>	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 type="text" value="1"/>	Each
<input type="text"/>	Gram
<input type="text"/>	Milliliter

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

## 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?

Has FDA granted waiver/exception/exemption for product?  If yes, attach documentation from FDA.

## ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Case/Bottle/Inner Pack:	0.1	1	4	1	4	1
Case:	1	6	4	4	96	12
Pallet:	2.3	16	5	7	560	24
UPC:	610	40	55	48	105600	253

## 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"/>	Box/Case/Bottle/Inner Pack	<input checked="" type="checkbox"/>	<input type="text"/>	00324979004075
<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	Case	<input type="checkbox"/>	<input type="text"/>	60324979004077
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Pallet	<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		<input type="checkbox"/>	<input type="text"/>	

## 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: