



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, Med Device:
 Rx Product/Proprietary Name:
 NDC: UPC:
 CVX Code: MVX Code:
 Description:
 Active ingredients:
 URL for Additional Product Information:
 Address: Address 2:
 City: State: Zip:
 Key Contact: Email:
 Phone Number: Fax:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 I. Freezer – between -25 and -10 C (-13° – 14° F)
 II. Cold – between 2 and 8 C (36° – 46° F)
 III. Cool – between 8 and 15 C (46° – 59° F)
 IV. Controlled Room – between 20 and 25 C (68° – 77° F)
 allows for excursions between 15 and 30 C (59° – 86° F)
 V. Avoid Excessive Heat – above 40 C (>104° F)
 VI. Other Temperature Range Requirement
 (write in)
 VII. No Requirement

b. Contact for temperature excursion questions:
 Name:
 Number:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

c. Special regulations for product in certain 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

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: II. Brand Name:
 III. Generic Equivalent for Brand:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes DUNS:
 Is product exempt from DSCSA? No
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? No If Yes, was original product purchased direct from mfr?
 Is product sold by manufacturer's exclusive distributor? No
 Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 Legend Device? No
 State Control? No
 ARCOS reportable? No
 Co-Licensed? No
 Controlled Substance? No
 Schedule No.?
 (incl. N for non-narcotic)
 Controlled Substance Code:
 Hazardous Material/Cytotoxic Agent? No
 Is Item...
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 Is it reverse numbered?

ORDER INFORMATION

Unit of Sale
 Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power Multi
 Other: Write In

What is the NDC selling unit?

 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 Each
 Inner/Cartron/Pack
 Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	42.3		3.19	1.68	0	
Box/ Carton:					0	
Case:	3.40 lbs	4.5	10	6.8	306	24
Pallet:	562 lbs	47	39	47	86151	160
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

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

Other Product Information

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

COST INFORMATION

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
<input type="text"/>	<input type="text"/>	<input type="text"/>

WHOLESALE USE ONLY:

Vendor #:
 Whsl. Code #:
 Fineline Code:

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

As of date:

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: