



# 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:

Phone Number:  Email:

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?

State Control?

ARCOS reportable?

Co-Licensed?

Controlled Substance?

Schedule No.?

(incl. N for non-narcotic)

Controlled Substance Code:

Hazardous Material/Cytotoxic Agent?

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:		
Box/ Carton:	0.04g	4.3125	2.875	1.1875	14.7231445	1
Case:	1.4 lbs	12.06	5.19	7.69	481.327866	24
Pallet:	274 lbs	48	40	52	99840	152
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

As of date:

## WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

Rx billing unit to pharmacy:

Each

Gram

Milliliter

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
  - Carcinogen
  - Reproductive Toxicant
  - Both
  - Warning appears on label
- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  No  
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?  No

(if yes, answer a-d below and provide SDS)

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

(if yes, identify method below)

- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

### ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level	How?	RFID	GTIN-14
Serialized?	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	00370710100827
If not, when?	<input type="text"/>	Box/ Carton	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	
Items aggregated to case?	<input type="text"/>	Case	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	40370710100825
		Pallet	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	80370710100823

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

### ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- Organic  Inorganic
- Antineoplastic  Steroid/Androgen
- Corrosive  Oxidizer
- Aerosol Class; Identify NFPA Storage Level:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  877-993-8779

Is product returnable for credit:

URL/Link to returns policy:  www.zydususa.com

Special regulations or returns requirements for this product in certain states?  No

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

- Ephedrine
- Pseudoephedrine
- Phenylpropanolamine
- Iodine (≥2.2%)
- Other:

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  No

Comments:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:  70710-1008-2

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

