



# 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, 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?  DUNS:

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?

Are any waivers granted for product ID/barcode?  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?

If Yes, how many of which package type?

Each

Inner/Carton/Pack

Case

## ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton:		5.31 Inches	2.36 Inches	2.16 Inches		10 Vials
Case:		14.17 Inches	6.33 Inches	11.61 Inches		24 cartons 6 x 4 Inner shippers
Pallet:		48 Inches	41.85 Inches	40 Inches		45 Shippers
UPC:	Case:					
	Carton:	355150188109				

## 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"/>
As of date: <input type="text"/>		

## 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?
  - b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Carcinogen
  - Reproductive Toxicant
  - Both
  - Warning appears on label
  - c. Contact Hazard?
  - d. Does this product require special clean-up instructions?   
(If yes, attach SDS with special instructions.)
  - e. Does the product contain DEHP?

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

- Is this product regulated for shipment by the DOT?
- Is this a reportable quantity?   
RQ Threshold:
- Is this a marine pollutant?
- 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#

- (if yes, answer a-d below and provide SDS)
- a. DOT Hazard Class
  - b. UN/ID Number
  - c. Packing Group
  - d. Inhalation Hazard?

- Is the product restricted for air shipment? If so, indicate restriction:
- Passenger
  - Cargo
  - Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Level	How?	GTIN-14			
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID <input type="checkbox"/> 10355150188106			
<input type="checkbox"/>	Box/ Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID <input type="checkbox"/> 00355150188109			
<input type="checkbox"/>	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID <input type="checkbox"/> 50355150188104			
<input type="checkbox"/>	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID <input type="checkbox"/> 70355150188108			

- ### ADD'L STORAGE INFORMATION
- Please check as appropriate for this product.
- Organic  Inorganic
  - Antineoplastic  Steroid/Androgen
  - Corrosive  Oxidizer
  - Aerosol Class; Identify NFPA Storage Level:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

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

- Listed Chemical (List I or II) (Indicate or Write-in below):
- Ephedrine
- Pseudoephedrine
- Phenylpropanolamine
- Iodine (≥2.2%)
- Other:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

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



# Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/>
Class of Trade Restriction:	Saturday Overnight receipt available:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	<b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
REMS or Registry Restrictions	Return Instructions
<b>REMS:</b> <input type="checkbox"/> REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="checkbox"/> Wholesale distributor support: <input type="checkbox"/> Provider Name: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/> DEA #: <input type="text"/> PCPDP #: <input type="text"/> NPI #: <input type="text"/> Comments: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments: <input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	<input type="text"/>