



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  Pre-Approval Supplement  Post Launch Change  New Drug

Final Version  Draft

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:   
 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?  No  Yes  
 Is this product to be shipped to customers on dry ice?  No  Yes  
 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?  No  Yes  
 d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light?  No  Yes  
 e. Shelf life:  
 Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

Is the Product...  
 a legend device?  No  Yes  
 reverse numbered?  No  Yes  
 co-licensed?  No  Yes  
 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?  Yes  No  
 If Unit Dose NDC, indicate NDC here:   
 Country of Origin:   
 Is this product covered under the Trade Agreements Act (TAA)?  No  Yes

## 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?  No  Yes  
 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?  Yes  No  
 If yes, select exemption:   
 Other exemption - Write in:   
 Is product repackaged?  No  Yes  
 Is product sold by manufacturer's exclusive distributor?  No  Yes  
 Has FDA granted waiver/exception/exemption for product?  No  Yes  
 GLN:   
 If Yes, was original product purchased direct from mfr?  No  Yes  
 If yes, attach documentation from FDA.

## ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.05		3	1.7		
Case:	2.05	10	4.4	6.1	0.155	24
Pallet:						4416
UPC:	Case:					
	Carton:					

## GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Soleable Unit	Quantity		GTIN-14
			Item	Unit	
<input checked="" type="checkbox"/> Yes	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/> 2D	<input checked="" type="checkbox"/> 1	Linear	00331722702300
<input checked="" type="checkbox"/> Yes	Case	<input checked="" type="checkbox"/> 2D	<input checked="" type="checkbox"/> 24	Linear	20331722702304
	Pallet	<input checked="" type="checkbox"/> 2D		Linear	
		<input type="checkbox"/> 2D		Linear	
		<input type="checkbox"/> 2D		Linear	
		<input type="checkbox"/> 2D		Linear	
		<input type="checkbox"/> 2D		Linear	
		<input type="checkbox"/> 2D		Linear	

## 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:

**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

Is the product a CA Prop 65 carcinogen? No

Is the product a CA Prop 65 reproductive toxicant? No

Does the product label bear a CA Prop 65 warning? No

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

Is this product regulated for shipment by DOT or IATA? No

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

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

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? No

(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#

**ADD'L STORAGE INFORMATION**

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No

If yes, indicate which:

Is it a scheduled listed chemical product? No

**CLASS OF TRADE RESTRICTION:**

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

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

**SDS Hazard Classification**

Organic  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

**Hazardous Waste Identification**

EPA Hazardous Waste Code:

**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?)

**REMS:**

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #: No

PCPDP #: No

NPI #: No

Comments:

**Registry:** No

Registry Program Contact Name:  Phone:

Comments:

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments?

**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"/> Yes <input type="checkbox"/> No b. Autofax <input type="checkbox"/> No <input type="checkbox"/> Yes Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes <input type="checkbox"/> No Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> No <input type="checkbox"/> Yes Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> No <input type="checkbox"/> Yes Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> case pack Supplier's Customer Service Number: <input type="text"/> 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> 2:30PM Eastern Shipping lead time of PO: <input type="text"/> 24/48 Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> No Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt cut off time: <input type="text"/> 2:30PM Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text"/> 2:30PM EST <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> No PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="checkbox"/> No <input type="checkbox"/> Yes Phone #: <input type="text"/> Fax: <input type="checkbox"/> Yes <input type="checkbox"/> No Fax #: <input type="text"/> 732-562-8788 EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> Yes Other fees apply: <input type="checkbox"/> No
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
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"/>	Contact # if product is received damaged: <input type="text"/> 732-529-0430 Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> No Is product order for restocking purposes? <input type="checkbox"/> No