



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Product  Post Launch Change

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:   
 City:   
 Key Contact:   
 Phone Number:   
 Product Therapeutic Classification:

Address 2:   
 State:  Zip:   
 Email:   
 Fax:

## 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?   
 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:  
 Initial shelf life at launch (if different):  Months

### ADDITIONAL PRODUCT INFORMATION

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product...   
 Is the Product...   
 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:  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

## 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:  
 Each  
 Gram  
 Milliliter

## 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?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exception/exemption for product?   
 If Yes, was original product purchased direct from mfr?   
 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:	0.1		3.5	1.5		
Case:	4.5	13	4.5	10	0.338	48
Pallet:						96
UPC:	Case:					
	Carton:					

## GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Soleable Unit	Quantity	GTIN-14	
				Item	Case
<input type="text" value="Yes"/>	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>	1	00331722828307	
<input type="text"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	48	20331722828301	
<input type="text" value="Yes"/>	<input type="checkbox"/> Pallet	<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			
		<input type="checkbox"/>			

## COST INFORMATION

Regular Cost:   
 Invoice Cost (WAC) (\$):   
 Federal Excise Tax Per Unit of Sale:   
 As of date:   
 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**

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> 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? Yes

If Yes, is it managed with a pharmacy registry? No

Website URL:

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

**REMS:** Yes

REMS Program Manager Name:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

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:**

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/> Eastern</p> <hr/> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/> Eastern</p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input style="width: 100%; height: 60px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>