



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: **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:  Address 2:

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?

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... Direct-Ship Only   
 Is the Product... Unit of Use

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

Yes	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?

If Yes, how many of which package type?

24 Bottles	Each
per Case	Inner/Carton/Pack
3 Cases	Case

**FOR GENERIC DRUG PRODUCTS**

Authorized Generic \*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:

II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Rx billing unit to pharmacy:

<input checked="" type="checkbox"/>	Each
<input type="checkbox"/>	Gram
<input type="checkbox"/>	Milliliter

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

**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?  If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?  If yes, attach documentation from FDA.

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.06	NA	2.8	1.6	#VALUE!	30 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	2	11.5	4.1	7.4	348.91	24 Bottles per Case
Pallet:	390	48	48	40	92160	173 per Pallet
UPC:	Case:	350228379304				
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized?	Yes	Level	Item	Saleable Unit	Quantity	GTIN-14
If not, when?	<input type="text"/>		Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	1	00350228379304
Items aggregated?	<input type="text" value="No"/>		Case	<input checked="" type="checkbox"/>	24	20350228379308
			Pallet			

**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?

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? \_\_\_\_\_  
 (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? No

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

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? \_\_\_\_\_  
 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? \_\_\_\_\_

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

Controlled Substance Code \_\_\_\_\_

Listed Chemical (List I or II) \_\_\_\_\_  
 If yes, indicate which: \_\_\_\_\_

Is it a scheduled listed chemical product? \_\_\_\_\_

### 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: \_\_\_\_\_

SDS Hazard Classification	
<input checked="" 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
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <span style="float: right;">_____</span>	
Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>	
If yes, indicate which: <span style="float: right;">_____</span>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	_____

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <span style="float: right;">No</span>	
If Yes, is it managed with a pharmacy registry? <span style="float: right;">_____</span>	
Website URL: <span style="float: right;">_____</span>	
Comments / Details: (For example, iPledge program?) <span style="float: right;">_____</span>	
<b>REMS:</b> <span style="float: right;">_____</span>	
REMS Program Manager Name:	_____
Supplier Manages REMS registry exclusively:	_____
Wholesale distributor support:	_____
Provider Name:	_____
Site Enrollment Number assigned by Supplier:	_____
Phone:	_____
DEA #:	_____
PCPDP #:	_____
NPI #:	_____

Comments \_\_\_\_\_

**Registry:** \_\_\_\_\_

Registry Program Contact Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Comments \_\_\_\_\_

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	1877-671-4307
Is product returnable for credit:	_____
URL/Link to returns policy:	_____
Special regulations or returns requirements for this product in certain states? <span style="float: right;">No</span>	
If so, which states? Other requirements? Comments? <span style="float: right;">_____</span>	

### 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"/></p> <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"/></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="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<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>	<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>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<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><input style="width: 100%; height: 80px;" type="text"/></p>
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	