



# 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:  Months

Initial shelf life at launch (if different):

**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 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?

<input type="text" value="1"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text"/>	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:

<input type="text"/>	Each
<input type="text"/>	Gram
<input type="text"/>	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		
Box/Carton/Bundle/Inner Pack:	0.08155	1.9685039	3.2283465	1.4173228	9.00710463	1
Case:	0.4628	4.488189	3.7401575	3.4645669	58.1580691	4
Pallet:	3.5925	11.653543	4.2125984	9.9212598	487.051494	24
UPC:	246.6276	41.433071	29.897638	36.397638	45087.6082	1440

UPC: Case:  Carton:

**GTIN PRODUCT INFORMATION**

Serialized?	Yes	Level		Quantity	GTIN-14
		Item	Saleable Unit		
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	1	00321922020120
Items aggregated?	<input type="text" value="Yes"/>	<input checked="" type="checkbox"/>	Case	4	10321922020127
		<input checked="" type="checkbox"/>	Pallet	24	30321922020121
		<input checked="" type="checkbox"/>		1440	50321922020125
		<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:

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

a. UN/Identification Number	UN1170
b. Proper Shipping Name	Ethanol Solution
c. DOT Hazard Class	3
d. Packing Group	II
e. Inhalation Hazard?	No

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
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <span style="border: 1px solid black; display: inline-block; width: 50px; height: 15px;"></span>	
Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>	
If yes, indicate which: <span style="border: 1px solid black; display: inline-block; width: 150px; height: 15px;"></span>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<span style="border: 1px solid black; display: inline-block; width: 150px; height: 15px;"></span>

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?  
 (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#

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;">No</span>	
Website URL: <span style="border: 1px solid black; display: inline-block; width: 150px; height: 15px;"></span>	
Comments / Details: (For example, iPledge program?) <span style="border: 1px solid black; display: inline-block; width: 100%; height: 15px;"></span>	
<b>REMS:</b> <span style="float: right;">No</span>	
REMS Program Manager Name: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>	Phone: <span style="border: 1px solid black; display: inline-block; width: 50px; height: 15px;"></span>
Supplier Manages REMS registry exclusively: <span style="border: 1px solid black; display: inline-block; width: 50px; height: 15px;"></span>	
Wholesale distributor support:	
Provider Name: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>	
Site Enrollment Number assigned by Supplier: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>	DEA #: <span style="float: right;">No</span>
	PCPDP #: <span style="float: right;">No</span>
	NPI #: <span style="float: right;">No</span>

ADD'L STORAGE INFORMATION	
Is the Product...	
Controlled Substance? <span style="float: right;">No</span>	
Controlled by State(s)? <span style="float: right;">No</span>	
ARCOS Reportable? <span style="float: right;">No</span>	
Schedule No. (inc. N for non-narcotic) <span style="border: 1px solid black; display: inline-block; width: 50px; height: 15px;"></span>	
Controlled Substance Code <span style="border: 1px solid black; display: inline-block; width: 50px; height: 15px;"></span>	
Listed Chemical (List I or II) <span style="float: right;">No</span>	
If yes, indicate which: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>	
Is it a scheduled listed chemical product? <span style="float: right;">No</span>	

Comments

**Registry:** No

Registry Program Contact Name:  Phone:

Comments

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">No</span>	
Restricted to retail pharmacy only: <span style="float: right;">No</span>	
Restricted to hospital, clinics, and physician offices only: <span style="float: right;">No</span>	
Restricted from US territories? (explain in comments) <span style="float: right;">No</span>	
Comments: <span style="border: 1px solid black; display: inline-block; width: 100%; height: 30px;"></span>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span> 919-767-3292	
Is product returnable for credit: <span style="float: right;">Yes</span>	
URL/Link to returns policy: <span style="border: 1px solid black; display: inline-block; width: 150px; height: 15px;"></span> Contact Manufacturer	
Special regulations or returns requirements for this product in certain states? <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>	
If so, which states? Other requirements? Comments? <span style="border: 1px solid black; display: inline-block; width: 100%; height: 30px;"></span>	

MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<span style="border: 1px solid black; display: inline-block; width: 100%; height: 100%;"></span>	

**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"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: 984-439-2761</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" value="144"/> Units</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" value="12pm"/> Eastern</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"/> Yes</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"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes</p> <p>Comments: <input style="width: 100%; height: 50px;" 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"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="919-767-3292"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text" value="Please contact manufacturer"/></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: 50px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 100px;" type="text"/>	