



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

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:  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?  
 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?  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		
Item:	0.1	NA	3	1.74	#VALUE!	90 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	3	11.5	4.2	7.2	347.76	24 Bottles per Case
Pallet:	275	48	54	40	103680	78 Cases per Pallet
UPC:	Case:	350228354905				
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized? If not, when? Items aggregated?	Yes <input type="text"/>	Level	Saleable Unit	Quantity	GTIN-14
	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	1	00350228354905
	<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	24	20350228354909
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
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	<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 #:   
 Finline 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?  
(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#

**SDS Hazard Classification**  
 Organic  
 Inorganic  
 Steroid/Androgen  
 Corrosive  
 Oxidizer  
 Contact Hazard  
 Aerosol Class; Identify NFPA Storage Level:  
Is the product a NIOSH hazardous drug? No  
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:  
Wholesale distributor support:  
Provider Name:  
Site Enrollment Number assigned by Supplier: DEA #: PCPDP #: NPI #:

Comments  
**Registry:**  
Registry Program Contact Name: Phone:  
Comments

**ADD'L STORAGE INFORMATION**  
Is the Product...  
Controlled Substance? Yes  
Controlled by State(s)? Yes  
ARCOS Reportable? No  
Schedule No. (inc. N for non-narcotic) V N  
Controlled Substance Code 2782  
Listed Chemical (List I or II) No  
If yes, indicate which:  
Is it a scheduled listed chemical product? No

**RETURN INSTRUCTIONS**  
Contact tel. # if product received damaged: 1877-671-6307  
Is product returnable for credit:  
URL/Link to returns policy:  
Special regulations or returns requirements for this product in certain states? No  
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 No  
Restricted to retail pharmacy only: Yes  
Restricted to hospital, clinics, and physician offices only: Yes  
Restricted from US territories? (explain in comments) No  
Comments: Not Applicable

**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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">a. EDI</td> <td style="width: 25%;"><input type="text"/></td> <td style="width: 25%;">Fax Number:</td> <td style="width: 25%;"><input type="text"/></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>	b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="text"/>	Phone No.:	<input type="text"/>	d. Phone only	<input type="text"/>	Site Address:	<input type="text"/>	e. Supplier Web Site only	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 60%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 15%;" type="text"/> Hours <input style="width: 15%;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>																						
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Phone:	<input style="width: 80%;" type="text"/>																								
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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 95%; height: 40px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt cut off time: <input style="width: 60%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 40%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="text"/>	Phone #:	<input type="text"/>	Fax:	<input type="text"/>	Fax #:	<input type="text"/>	EDI:	<input type="text"/>				
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																								
<p>Patient Procedure Date: <input style="width: 60%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 80%;" type="text"/></p> <p>Physician State License #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 80%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																								
Miscellaneous Notes:																									
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