



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... Direct-Ship Only

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

<input checked="" type="checkbox"/>	Bottle
<input type="checkbox"/>	Box/Carton
<input type="checkbox"/>	Ampule
<input type="checkbox"/>	Glass
<input type="checkbox"/>	Tube
<input type="checkbox"/>	Vial Liquid Sgl
<input type="checkbox"/>	Vial Liquid Multi
<input type="checkbox"/>	Vial Powder Sgl
<input type="checkbox"/>	Vial Powder Multi
<input type="checkbox"/>	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="24"/>	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?

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

Rx billing unit to pharmacy:

<input type="text"/>	Each
<input type="text"/>	Gram
<input type="text"/>	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

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?

GLN:

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		
0.14	1.9	4	1.9	14.44		
Box/Carton/Bundle/Inner Pack:				0		
Case:	4.33	11.5	5	7.75	445.63	24
Pallet:				0		
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14
				<input checked="" type="checkbox"/>	<input type="checkbox"/>		
<input type="text" value="Yes"/>	<input type="text"/>	<input type="text"/>	Item	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1	00359746711900
			Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>	<input type="checkbox"/>		
			Case	<input checked="" type="checkbox"/>	<input type="checkbox"/>	24	40359746711908
			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"/>		
				<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?
 (If yes, attach SDS with special instructions.) No

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) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

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: <input type="text"/>	
Is the product a NIOSH hazardous drug? No	
If yes, indicate which: <input type="text"/>	

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#

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

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

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)	<input type="text"/>
Controlled Substance Code	<input type="text"/>
Listed Chemical (List I or II)	No
If yes, indicate which:	<input type="text"/>
Is it a scheduled listed chemical product?:	<input type="text"/>

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	No
Restricted to hospital, clinics, and physician offices only:	No
Restricted from US territories? (explain in comments)	No
Comments:	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text" value="(410) 912-3722"/>
Is product returnable for credit:	Yes
URL/Link to returns policy:	<input type="text" value="www.cadista.com"/>
Special regulations or returns requirements for this product in certain states?	<input type="text"/>
If so, which states? Other requirements? Comments?	<input type="text"/>

MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	

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: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="2"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="2"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Phone No.:</td> <td colspan="2"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Site Address:</td> <td colspan="2"><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 50px;" type="text" value="24"/></p> <p>Supplier's Customer Service Number: <input style="width: 100%;" type="text" value="(410) 912-3722"/></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="checkbox"/>	Yes				b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>		c. Fax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>		d. Phone only	<input type="checkbox"/>		Phone No.:	<input style="width: 100%;" type="text"/>		e. Supplier Web Site only	<input type="checkbox"/>		Site Address:	<input style="width: 100%;" type="text"/>		Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 150px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
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Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%;"> <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>Priority Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 30%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%;">Phone #:</td> <td style="width: 30%;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 100%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td colspan="3"><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" 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 style="width: 100%;" type="text"/>	Phone #:	<input style="width: 100%;" type="text"/>	Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>	EDI:	<input style="width: 100%;" type="text"/>														
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Class of Trade Restriction:	Return Instructions																																		
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></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:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input style="width: 100%;" type="text"/></p> <p>Physician Name: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100%;" type="text"/></p> <p>Physician State License #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																																		
Miscellaneous Notes:																																			
<input style="width: 100%; height: 100px;" type="text"/>																																			