



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

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: Months

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... Neither

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 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 checked="" type="checkbox"/>	Other: Write In
<input type="checkbox"/>	Jar

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" value=""/>	Inner/Carton/Pack
<input type="text" value=""/>	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="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		
Box/Carton/Bundle/Inner Pack:	1.075	3.74	4.212	3.74	58.9157712	1
Case:	NA	NA	NA	NA	NA	NA
Pallet:	50.135	19.488	13.779	12.204	3277.08096	45
UPC:	745.98	47.99	60.352	40	115851.699	630

UPC:

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit	Quantity	GTIN-14	
						Item	Case
<input type="text" value="Yes"/>	<input type="text" value=""/>	<input type="text" value=""/>	Box/Carton/Bundle/Inner Pack	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="00364380901907"/>	<input type="text" value=""/>
			Case	<input type="text" value="45"/>	<input type="text" value="45"/>	<input type="text" value="50364380901902"/>	<input type="text" value=""/>
			Pallet	<input type="text" value="630"/>	<input type="text" value="630"/>	<input type="text" value="70364380901906"/>	<input type="text" value=""/>
				<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
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				<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

COST INFORMATION

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

WHOLESALE USE ONLY:

Vendor #:
 Whsl. Code #:
 Fine Line 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

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen 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: No

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

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

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> <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 type="text"/></p> <p>Supplier's Customer Service Number: <input 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 type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input 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 type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</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="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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e. Supplier Web Site only	<input type="text"/>																								
Name:	<input type="text"/>																								
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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 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: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input 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>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input 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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Class of Trade Restriction:	Return Instructions																								
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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="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																								
Miscellaneous Notes:																									
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