



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

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 Controlled Room – between 20 and 25 C (68° – 77° F)

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...

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"/>	x	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 checked="" type="checkbox"/>	x	Each
<input type="checkbox"/>		Gram
<input type="checkbox"/>		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:	0.3	1.5	5	1.5	11.25	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	24.3	14	7	12	1176	81
Pallet:					0	
UPC:						
	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

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

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

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?

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 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? No
 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 #:

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

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:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: No

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

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: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>No</u></td> <td style="width: 10%;"></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;"><u>Yes</u></td> <td>Fax Number:</td> <td colspan="3"><u>8007549550</u></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax Number:</td> <td colspan="3"><u>8007549550</u></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><u>Yes</u></td> <td>Phone No.:</td> <td colspan="3"><u>8667477365</u></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><u>No</u></td> <td>Site Address:</td> <td colspan="3"></td> </tr> </table> <p>Minimum Order Quantity: <u>24</u></p> <p>Supplier's Customer Service Number: <u>8667477365</u></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><u></u></td> </tr> <tr> <td>Phone:</td> <td><u></u></td> </tr> </table>	a. EDI	<u>No</u>					b. Autofax	<u>Yes</u>	Fax Number:	<u>8007549550</u>			c. Fax	<u>Yes</u>	Fax Number:	<u>8007549550</u>			d. Phone only	<u>Yes</u>	Phone No.:	<u>8667477365</u>			e. Supplier Web Site only	<u>No</u>	Site Address:				Name:	<u></u>	Phone:	<u></u>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <u>4:00pm. CST</u></p> <p>Shipping lead time of PO: <u>2</u> Hours <u></u> Days</p> <p>Ships same day for next day receipt: <u>No</u></p> <p>Ships for second day receipt: <u>No</u></p> <p>Ships regular ground for 3-10 days receipt: <u>Yes</u></p>
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Name:	<u></u>																																		
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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: <u>No</u></p> <p>Drop Ship service fee billed with each order: <u>No</u></p> <p>Drop Ship miscellaneous fees billed: <u>No</u></p> <p>Comments: <u></u></p>	<p>Overnight receipt available: <u>Yes</u></p> <p>PO Receipt cut off time: <u>4:00pm CST</u></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <u>No</u></p> <p>PO Receipt Cut off time: <u></u></p> <p>Saturday Overnight receipt available: <u>No</u></p> <p>PO Receipt Cut off time: <u></u></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td><u></u></td> <td style="width: 20%;">Phone #:</td> <td><u></u></td> </tr> <tr> <td>Fax:</td> <td><u></u></td> <td>Fax #:</td> <td><u></u></td> </tr> <tr> <td>EDI:</td> <td><u></u></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <u></u></p> <p>Other fees apply: <u></u></p>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	Phone:	<u></u>	Phone #:	<u></u>	Fax:	<u></u>	Fax #:	<u></u>	EDI:	<u></u>														
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Other Data Information Required to Process PO:	Return Instructions																																		
<p>Patient Procedure Date: <u></u></p> <p>Physician Name: <u></u></p> <p>Physician/Clinic Phone #: <u></u></p> <p>Physician State License #: <u></u></p> <p>Physician/Clinic DEA #: <u></u></p> <p>Physician/Clinic Specialty: <u></u></p>	<p>Contact # if product is received damaged: <u>8667477365</u></p> <p>Is product returnable for credit: <u>No</u></p> <p>URL/Link to returns policy: <u></u></p> <p>Special regulations or returns requirements for this product in certain states? <u></u></p> <p>If so, which states? Other requirements? Comments? <u></u></p>																																		
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<p><u></u></p>	<p>Is product order for scheduled patient procedure? <u>No</u></p> <p>Is product order for restocking purposes? <u>No</u></p>																																		