



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item 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:
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
 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?

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? If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.1385	2.2	4.488	1.18	11.650848	1
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	5.025	9.212	5.11	7.48	352.108434	24
Pallet:	797.84	48.11	40.157	39.448	76211.6926	3600
UPC:	Case:					
	Carton:	<input type="text" value="321922003017"/>				

GTIN PRODUCT INFORMATION

	Level		Quantity	GTIN-14
	Item	Saleable Unit		
Serialized? <input type="text" value="Yes"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00321922003017
If not, when?				
Items aggregated? <input type="text" value="Yes"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	24	30321922003018
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3600	50321922003012

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? No
(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?
 (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)

If yes, indicate which:

Is it a scheduled listed chemical product?

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

<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 style="width: 100px;" type="text"/>	
Is the product a NIOSH hazardous drug? No	
If yes, indicate which: <input style="width: 100%;" type="text"/>	

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

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

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: 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> <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></td> <td>Fax Number:</td> <td colspan="4" style="border: 1px solid black;"></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="4" style="border: 1px solid black;">984-439-2761</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="4" style="border: 1px solid black;"></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="4" style="border: 1px solid black;"></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 90%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Phone:</td> <td style="border: 1px solid black;"></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes						b. Autofax	<input type="checkbox"/>		Fax Number:					c. Fax	<input type="checkbox"/>	Yes	Fax Number:	984-439-2761				d. Phone only	<input type="checkbox"/>		Phone No.:					e. Supplier Web Site only	<input type="checkbox"/>		Site Address:					Name:		Phone:		<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 150px;" type="text" value="2:00 PM"/> Eastern</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" value="Yes"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text" value="Yes"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text" value="Yes"/></p> <p>Comments: <div style="border: 1px solid black; height: 60px; width: 100%;"></div></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%; border-collapse: collapse;"> <tr><td><input type="checkbox"/> Monday</td></tr> <tr><td><input type="checkbox"/> Tuesday</td></tr> <tr><td><input type="checkbox"/> Wednesday</td></tr> <tr><td><input type="checkbox"/> Thursday</td></tr> <tr><td><input type="checkbox"/> 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%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%; border: 1px solid black;"></td> <td style="width: 20%;">Phone #:</td> <td style="width: 20%; border: 1px solid black;"></td> </tr> <tr> <td>Fax:</td> <td style="border: 1px solid black;"></td> <td>Fax #:</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>EDI:</td> <td style="border: 1px solid black;"></td> <td></td> <td></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:		Phone #:		Fax:		Fax #:		EDI:																														
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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: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p>Contact # if product is received damaged: <input style="width: 150px;" 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: 150px;" 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? <div style="border: 1px solid black; height: 30px; width: 100%;"></div></p>																																												
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																												
<p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" 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>																																												
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