



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:** **MXV 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

<input type="checkbox"/>	Bottle
<input checked="" 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 Power Multi
<input type="checkbox"/>	Other: Write In

What is the NDC selling unit?

Minimum order quantity?

If Yes, how many of which package type?

<input type="text"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text" value="1"/>	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:

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

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:	0.0704	5.748	1.181	0.984	6.67977379	1
Box/Carton/Bundle/Inner Pack:	0.851	5.944	3.74	4.133	91.8789045	12
Case:	15.917	13.385	8.11	12.55	1362.33199	144
Pallet:	617.104	41.574	40.629	39.09	66027.3117	5184
UPC:	Case: <input type="text"/>					
	Carton: <input type="text" value="321922031058"/>					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Yes	Level	Item	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack				00321922031058
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Case				10321922031055
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Pallet				30321922031059
<input type="checkbox"/>	<input type="checkbox"/>					50321922031053
<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:

Wholesaler 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? No

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?

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?

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"/> Inorganic <input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" 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: <input style="width: 100%;" type="text"/>

REMS or REGISTRY RESTRICTIONS
Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/> Website URL: <input style="width: 100%;" type="text"/>
Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/>
REMS: No REMS Program Manager Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/> Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/> Wholesale distributor support: Provider Name: <input style="width: 100%;" type="text"/> Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/>
DEA #: <input style="width: 100%;" type="text"/> PCDP #: <input style="width: 100%;" type="text"/> NPI #: <input style="width: 100%;" type="text"/>

Comments <input style="width: 100%; height: 20px;" type="text"/>
Registry: <input style="width: 100%;" type="text"/>
Registry Program Contact Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/>
Comments <input style="width: 100%; height: 20px;" type="text"/>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <input style="width: 100%; text-align: center; border: 1px solid black;" type="text" value="919-767-3292"/>
Is product returnable for credit: Yes
URL/Link to returns policy: <input style="width: 100%;" type="text"/>
Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/>
If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/>

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> <p>a. EDI <input type="checkbox"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: 984-439-2761</p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text" value="2:00 PM"/> Eastern</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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
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="checkbox"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input style="width: 100%; height: 80px;" type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>