



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: 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...

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 Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Power 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? (Write-in, e.g. 1 Vial)

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?

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		
Box/Carton/Bundle/Inner Pack:	0.08	1.87	3.77	1.87	13.183313	
Case:	7.05	15.24	5.51	11.49	964.842876	48
Pallet:					0	
UPC:						

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	Unit		
<input checked="" type="checkbox"/>	<input type="text" value="Yes"/>	<input type="text"/>	<input checked="" type="checkbox"/>	Item	1	00359746282301
			<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	48	40359746282309
			<input checked="" type="checkbox"/>	Case		
			<input checked="" type="checkbox"/>	Pallet		

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?

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 Is the product a CA Prop 65 carcinogen?
 Is the product a CA Prop 65 reproductive toxicant?
 Does the product label bear a CA Prop 65 warning?

c. Contact Hazard?

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

Is this product regulated for shipment by DOT or IATA?
 (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?

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? <input type="checkbox"/>	
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?
 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#

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

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry? <input type="checkbox"/>	
Website URL: <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS: <input type="checkbox"/> No	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: <input type="checkbox"/>	
Wholesale distributor support: 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? <input type="checkbox"/>	No
Controlled by State(s)? <input type="checkbox"/>	<input type="checkbox"/>
ARCOS Reportable? <input type="checkbox"/>	<input type="checkbox"/>
Schedule No. (inc. N for non-narcotic) <input type="text"/>	<input type="checkbox"/>
Controlled Substance Code <input type="text"/>	<input type="checkbox"/>
Listed Chemical (List I or II) <input type="checkbox"/>	<input type="checkbox"/>
If yes, indicate which: <input type="text"/>	
Is it a scheduled listed chemical product? <input type="checkbox"/>	

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 <input type="checkbox"/>	
Restricted to retail pharmacy only: <input type="checkbox"/>	
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/>	
Restricted from US territories? (explain in comments) <input type="checkbox"/>	
Comments: <input type="text"/>	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text"/>	
Is product returnable for credit: <input type="checkbox"/>	
URL/Link to returns policy: <input type="text"/>	
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"/>	



Standard Pharmaceutical Product Information (Page 3)

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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> Yes Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text" value="48"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>