



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, Med Device:

Rx Product/Proprietary Name:

NDC: UPC:

CVX Code: MVX Code:

Description:

Active ingredients:

URL for Additional Product Information:

Address: Address 2:

City: State: Zip:

Key Contact:

Phone Number: Email:

Fax:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

I. Freezer – between -25 and -10 C (-13° – 14° F)

II. Cold – between 2 and 8 C (36° – 46° F)

III. Cool – between 8 and 15 C (46° – 59° F)

IV. Controlled Room – between 20 and 25 C (68° – 77° F)
allows for excursions between 15 and 30 C (59° – 86° F)

V. Avoid Excessive Heat – above 40 C (>104° F)

VI. Other Temperature Range Requirement
(write in)

VII. No Requirement

b. Contact for temperature excursion questions:

Name:

Number:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

c. Special regulations for product in certain 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

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: II. Brand Name:

III. Generic Equivalent for Brand:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes DUNS:

Is product exempt from DSCSA? No

If yes, select exemption:

Other exemption - Write in:

Is product repackaged? No If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor? No

Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct Ship Item

Legend Device? No

State Control? No

ARCOS reportable? No

Co-Licensed? No

Controlled Substance? No

Schedule No.?

(incl. N for non-narcotic)

Controlled Substance Code:

Hazardous Material/Cytotoxic Agent? No

Is Item...

If Unit Dose, is item bar coded to unit dose for hospital scanning?

Is it reverse numbered?

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? Yes

If Yes, how many of which package type?

Each

Inner/Cartron/Pack

Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	0.04g	4.3125	2.875	1.1875	14.7231445	1
Case:	1.4 lbs	12.06	5.19	7.69	481.327866	24
Pallet:	274 lbs	48	40	52	99840	152
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

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

Rx billing unit to pharmacy:

Each

Gram

Milliliter

Other Product Information

Size/Strength/Form:

Product Shape:

Product Color:

Product Imprint:

COST INFORMATION

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$93.59	

As of date:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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
 - Carcinogen
 - Reproductive Toxicant
 - Both
 - Warning appears on label
- 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

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? No

(if yes, answer a-d below and provide SDS)

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?

(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#

- a. DOT Hazard Class
- b. UN/ID Number
- c. Packing Group
- d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level	How?	GTIN-14
Serialized?	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID 00370710100926
If not, when?	<input type="text"/>	Box/ Carton	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Items aggregated to case?	<input type="text"/>	Case	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID 40370710100924
		Pallet	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID 80370710100922

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

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?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- Organic Inorganic
- Antineoplastic Steroid/Androgen
- Corrosive Oxidizer
- Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

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

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

- Ephedrine
- Pseudoephedrine
- Phenylpropanolamine
- Iodine (≥2.2%)
- Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: 70710-1009-2

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

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Comments:



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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"/> <input type="text"/> b. Autofax <input type="checkbox"/> <input type="text"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> <input type="text"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> <input type="text"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> <input type="text"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> 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"/>	
REMS or Registry Restrictions	Return Instructions
REMS: <input type="checkbox"/> REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="checkbox"/> Wholesale distributor support: <input type="checkbox"/> 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"/> Comments: <input type="text"/> Registry: <input type="checkbox"/> Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments: <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"/>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
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"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> Miscellaneous Notes: <input type="text"/>