



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

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

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	1.32	NA	7.8	4.4	#VALUE!	500 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	17	15.2	9.7	11.5	1695.56	12 Bottles per Case
Pallet:	1060	48	54	40	103680	60 Cases per Pallet
UPC:	Case:	350228107058				
	Carton:					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Yes <input type="text"/>	Level	Saleable Unit	Quantity	GTIN-14
	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	1	00350228107051
	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack			
	<input checked="" type="checkbox"/>	Case		12	20350228107055
		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? 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.)
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)

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?
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
 Inorganic
 Steroid/Androgen
 Corrosive
 Oxidizer
 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?
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

ADD'L STORAGE INFORMATION
Is the Product...
Controlled Substance? No
Controlled by State(s)? No
ARCOS Reportable?
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?:

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: 1877-671-6307
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states? No
If so, which states? Other requirements? Comments?

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

