



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

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:

UDI CVX Code: UPC:

UVI 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 Requirements (write in)

Is this product to be shipped to customers on ice?

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

b. Contact for temperature excursion questions:
 Name:
 Number:
 Group Email:

c. Special regulations for product in any states?
 Special returns requirements for this product? See Return Policy

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

The product is?
 a legend device?
 if yes, enter class #
 a product kit?
 if yes, list NDC's of component parts reverse numbered?
 co-licensed?
 latex-free?
 preservative-free?
 corectional institution block?
 opioid?
 Cannabinoid?
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate here:

Is the Product...
 Is the Product...
 Orphan Drug Status
 FDA Approval Status
 Allergens Present:
 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?:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

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, attach documentation from FDA

GLN:
 GCP:

If Yes, was original product purchased direct from mfg?

Provide source manufacturer for repackaged product

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

Rx billing unit to pharmacy Each Gram Milliliter

ITEM AND PACKING INFORMATION

Item:	Dimensions (US msmts.)				Volume (Cube)	Saleable # Pieces:
	Weight Lbs.	Depth	Height	Width		
Box/Carton/Bundle / Inner Pack:	0.236	6.1	2.09	3.46	44.11154	1
Case:	17	19.4	15.5	13.8	4149.66	72
Pallet:						

GTIN PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	GTIN-14
X Item	1		00303787300531	00303787300531
Box/Carton/Bundle/Inner Pack				
X Case	72		20303787300535	
Pallet				

COST INFORMATION

Regular Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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?

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-S
- Special Provision (listed in Column 7 of 49 CFR 172.101);

SP# **ADD'L STORAGE INFORMATION****Is the Product...**

- Controlled Substance? Controlled Substance Code
- Controlled by State(s)? Listed Chemical (List I or II)
- ARCOS Reportable? If yes, indicate which:
- Schedule No. 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 hospitals, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is this product a NIOSH hazardous drug? Yes
 If yes, indicate which: **Hazardous Waste Identification**

EPA Hazardous Waste Code: N/A

Waste Characteristics: **REMS or REGISTRY RESTRICTIONS****Is there a REMS on this product?**If Yes, is it managed with a pharmacy registry? Website URL: Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) **REMS:**

REMS Program Manager Name:

Supplier Manages REMS registry exclusively

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone: DEA #: NCPDP#: NPI #: Comments: Registry: Registry Program Contact Name: Phone: Comments: **RETURN INSTRUCTIONS**Contact tel. # if product received damaged: Is product returnable for credit: 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:**

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"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone Only <input type="checkbox"/></p> <p>e. Supplier Web Site Only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p style="text-align: right;">Name: <input type="text"/></p> <p style="text-align: right;">Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></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="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Overnight receipt available <input type="text"/></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>
Class of Trade Restriction:	Priority Overnight PO Processing
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in the comments) <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input 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="text"/></p> <p>URL/Link to return policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input style="width: 100%; height: 100px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>