



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: UPC:

UDI CVX Code: 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?

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:

GLN:
GCP:

Is product repackaged?
If Yes, was original product purchased direct from mfg?
Provide source manufacturer for repackaged product

Is product sold by manufacturer's exclusive distributor?
Has FDA granted waiver/exception/exemption for product?
If Yes, attach documentation from FDA

GTIN PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	GTIN-14
X Item	1		00303787307530	00303787307530
Box/Carton/Bundle/Inner Pack				
X Case	72		20303787307534	
Pallet				

ITEM AND PACKING INFORMATION

Item:	Dimensions (US msmts.)				Volume (Cube)	Saleable # Pieces:
	Weight Lbs.	Depth	Height	Width		
Box/Carton/Bundle / Inner Pack:	0.3	6.2	3.5	2.4	52.08	1
Case:	21.45	19.2	15.3	15.2	4465.152	72
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?
 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 receipt available:
<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>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time <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 style="text-align: center;">If so, which states? Other requirements? Comments?</p> <p><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>