



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: **Application:**
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):
Medical Device Class, if applicable:
DUNS:
Proprietary Name (If Applicable) and Established Name:
Selling Unit NDC: **Unit of Use NDC:** **UPC:**
UDI **CVX Code:** **MXV 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:

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range
 Other Temperature Range Requirement (write in)
 Notes
 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: Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="text" value="No"/>	Is the Product... <input type="text" value="Direct-Ship Only"/>	Size:	<input type="text" value="1000ct"/>
if yes, enter class # <input type="text"/>	Is the Product... <input type="text" value="Neither"/>	Strength:	<input type="text" value="50mcg"/>
a product kit? <input type="text" value="No"/>	Orphan Drug Status <input type="text"/>	Dosage Form:	<input type="text" value="Tablet"/>
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape:	<input type="text" value="capsule shaped, biconvex tablets"/>
co-licensed? <input type="text" value="No"/>	Allergens Present <input type="text"/>	Product Color:	<input type="text" value="White"/>
latex-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="USA"/>	Product Imprint:	<input on="" other="" side."="" the="" type="text" value="plain on one side and debossed 'score line 2"/>
preservative-free? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>		
correctional institution block? <input type="text" value="No"/>			
opioid? <input type="text" value="No"/>			
Cannabinoid? <input type="text" value="No"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			
If Unit Dose, indicate NDC here: <input type="text"/>			

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 1000 tablets"/>
<input type="checkbox"/> Box/Carton	<input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/>
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In <input type="text"/>	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable
I. Orange Book Rating:
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?
 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 mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
<input type="text" value="0.33"/>	<input type="text" value="2.25"/>	<input type="text" value="2.25"/>	<input type="text" value="4.25"/>	<input type="text" value="21.52"/>	<input type="text" value="1"/>	
Box/Carton/Bundle/Inner Pack:						
Case:	<input type="text" value="8.5"/>	<input type="text" value="14.5"/>	<input type="text" value="10"/>	<input type="text" value="725"/>	<input type="text" value="24"/>	
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722285100"/>	<input type="text"/>
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>	<input type="text"/>	<input type="text" value="10331722285107"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
Invoice Cost (WAC) (\$)
 As of date:
Vendor #:
Whsl. Code #:
Fineline Code:



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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?
 - 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.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (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 this product regulated for shipment by 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 No
- Cargo No
- Passenger & Cargo No

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?

- 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#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes
- Controlled Substance Code
- Controlled by State(s)? No Yes
- Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required No Yes

REMS: REMS Program Manager Name: Phone:

Comments:

Registry: Registry Program Contact Name: Phone:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes No

URL/Link to returns policy: contact - customerservice@camberpharma.com

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

If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

