



# 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:  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:

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range   
 Other Temperature Range Requirement   
 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? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
co-licensed?	<input type="text"/>	FDA Approval Status	<input type="text"/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Corn, Alcohol, Animal, Sugar, Dye"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="USA"/>
correctional institution block? opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
Cannabinoid?	<input type="text" value="No"/>	Size:	<input type="text" value="100 ct"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Strength:	<input type="text" value="5 mg"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Dosage Form:	<input type="text" value="Extended-release, hard gelatin capsule"/>
		Product Shape:	<input type="text" value="Capsule"/>
		Product Color:	<input type="text" value="Light brown cap and white opaque body"/>
		Product Imprint:	<input type="text" value="Imprinted with 'M5' on cap and 'AC' on body in black ink"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 100 Capsules"/>
<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 Powder Multi	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 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?  Rx billing unit to pharmacy:  
 (Write-in, e.g. 1 Vial)  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:   
 GCP:   
 Is product repackaged?  If yes, was original product purchased direct from mfr?   
 Is product sold by manufacturer's exclusive distributor?  Provide source manufacturer for repackaged product   
 Has FDA granted waiver/exemption/exemption for product?

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.1	2	2	3.5	14	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	2.8	12.25	8.37	4	410.13	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="00331722229012"/>	<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="10331722229019"/>	<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 #:   
 Finline 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
- Cargo
- Passenger & Cargo

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

### 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:  Yes  No
- Restricted to hospital, clinics, and physician offices only:  Yes  No
- Restricted from US territories? (explain in comments)  Yes  No

Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

\*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="text" value="No"/>
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="text" value="No"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<input type="text" value="No"/>
If Yes, is it managed with a pharmacy registry? Website URL:	<input type="text"/>
Med Guide Required	<input type="text" value="No"/>
Limited Distribution Requirement	<input type="text"/>
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	<input type="text" value="No"/>
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="text"/>
Wholesale distributor support:	<input type="text"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
Phone:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
<b>Registry:</b>	<input type="text" value="No"/>
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text" value="1-866-827-3647"/>
Is product returnable for credit:	<input type="text" value="Yes"/>
URL/Link to returns policy:	<input type="text" value="contact - customerservice@camberpharma.com"/>
Special regulations or returns requirements for this product in certain states?	<input type="text" value="Yes"/>
If so, which states? Other requirements? Comments?	<input type="text"/>
DEA Form 222 or its electronic equivalent is required for all returns in all states.	<input type="text"/>



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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"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <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 <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <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"/>	
Other Data Information Required to Process PO:	Return Instructions
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"/>	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"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>