



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 (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: Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit? if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="text" value="No"/> <input type="text"/> <input type="text" value="No"/> <input type="text"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text" value="No"/>	Is the Product... Direct-Ship Only Is the Product... Unit of Use Orphan Drug Status FDA Approval Status Allergens Present Country of Origin	<input type="text" value="Direct-Ship Only"/> <input type="text" value="Unit of Use"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text" value="India"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="text"/> <input type="text"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
		Size:	<input type="text" value="30ct"/>
		Strength:	<input type="text" value="14mg"/>
		Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="Round, Round Convex"/>
		Product Color:	<input type="text" value="White to Off White"/>
		Product Imprint:	<input type="text" value="Debossed with 'H' on one side and 'T41'"/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 30 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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

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:

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		
Item/Each:	0.064	1.500	1.500	2.334	5.251	1
Box/Carton/Bundle/Inner Pack:	-	-	-	-	-	-
Case:	2.003	9.64	6.49	3.77	235.86	24
Pallet:	533.98	47.244	39.37	47.244	87,873.66	250

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" value="00331722247306"/>	<input type="text" value="00331722247306"/>
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>		<input type="text" value="20331722247300"/>	
<input type="checkbox"/> Pallet				

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
- 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?

- (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	
<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"/>	NFPA Storage Level: <input type="text"/>
Is the product a NIOSH hazardous drug? <input type="checkbox"/> Yes	Group 2 items (non-antineoplastic that meets a hazard criterion) <input type="text"/>

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

ADD'L STORAGE INFORMATION

Is the Product... Controlled Substance? <input type="checkbox"/> No	Controlled Substance Code <input type="text"/>
Controlled by State(s)? <input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No
ARCOS Reportable? <input type="checkbox"/> No	If yes, indicate which: <input type="text"/>
Schedule No. <input type="text"/>	Is it a scheduled listed chemical product?: <input type="checkbox"/> No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes
Restricted to retail pharmacy only: <input type="checkbox"/> No
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No
Restricted from US territories? (explain in comments) <input type="checkbox"/> No

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: <input type="text"/>	1-866-827-3647
Is product returnable for credit: <input type="checkbox"/> Yes	
URL/Link to returns policy: <input type="text"/>	contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No
If so, which states? Other requirements? Comments? <input type="text"/>

MISCELLANEOUS NOTES and/or Image of Product Barcode:

