



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION

Company Name: Application:
 Application Number for NDA/ANDA/BLA; PMA/510(k): NDA 505(b) Type:
 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:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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?	<input type="text" value="No"/>	Is the Product... Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
if yes, enter class # a product kit?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Dairy, Lactose, Casein"/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
correctional institution block? opioid?	<input type="text" value="No"/>	Size:	<input type="text" value="1000 ct"/>
Cannabinoid?	<input type="text" value="No"/>	Strength:	<input type="text" value="80 mg"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Dosage Form:	<input type="text" value="Film coated tablet"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Product Shape:	<input type="text" value="Oval, biconvex"/>
		Product Color:	<input type="text" value="White to off-white"/>
		Product Imprint:	<input type="text" value="Debossed with '80' on one side
and 'A 56' on other side"/>

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?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code:

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		
Box/ Carton/ Bundle/ Inner Pack:	3	5	5	7	175	1
Case:	38.1	20.5	15.75	8	2583	12
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722427104	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	12		20331722427108	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:



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Version 2024

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? 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

NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

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

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS: No Yes

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments:

Registry: No Yes

Registry Program Contact Name: Phone:

Comments:

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:



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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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only <p>Minimum Order Quantity:</p> <p>Supplier's Customer Service Number:</p> <p>Contracted 3PL company / contact #: Name: Phone:</p>	<p>Purchase order daily receipt cut off time by supplier Cut off time:</p> <p>Shipping lead time of PO: Hours Days</p> <p>Ships same day for next day receipt:</p> <p>Ships for second day receipt:</p> <p>Ships regular ground for 3-10 days receipt:</p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order:</p> <p>Drop Ship service fee billed with each order:</p> <p>Drop Ship miscellaneous fees billed:</p> <p>Comments:</p>	<p>Overnight receipt available:</p> <p>PO Receipt cut off time:</p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available:</p> <p>PO Receipt Cut off time:</p> <p>Saturday Overnight receipt available:</p> <p>PO Receipt Cut off time:</p> <p>Order receipt method: Phone: Phone #: Fax: Fax #: EDI:</p> <p>Overnight Fees apply: Other fees apply:</p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices</p> <p>Restricted to retail pharmacy only:</p> <p>Restricted to hospital, clinics, and physician offices only:</p> <p>Restricted from US territories? (explain in comments)</p> <p>Comments:</p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date:</p> <p>Physician Name:</p> <p>Physician/Clinic Phone #</p> <p>Physician State License #</p> <p>Physician/Clinic DEA #:</p> <p>Physician/Clinic Specialty:</p>	<p>Contact # if product is received damaged:</p> <p>Is product returnable for credit:</p> <p>URL/Link to returns policy:</p> <p>Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?</p>
Miscellaneous Notes:	
<p> </p>	
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure?</p> <p>Is product order for restocking purposes?</p>	