



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
 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="30ct"/> | |
| if yes, enter class # <input type="text"/> | Is the Product... <input type="text" value="Neither"/> | Strength: <input type="text" value="10mg"/> | |
| a product kit? <input type="text" value="No"/> | Orphan Drug Status <input type="text"/> | Dosage Form: <input type="text" value="Oral Solid - 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="Round"/> | |
| co-licensed? <input type="text" value="No"/> | Allergens Present <input type="text" value="Lactose , Corn"/> | Product Color: <input type="text" value="White to off white"/> | |
| latex-free? <input type="text" value="Yes"/> | Country of Origin <input type="text" value="India"/> | Product Imprint: <input type="text" value="Lower punch '19' and Upp"/> | |
| preservative-free? <input type="text" value="No"/> | Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/> | | |
| 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" value="No"/> | | | |
| 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 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 | |
| <input type="checkbox"/> Vial Liquid Multi | |
| <input type="checkbox"/> Vial Powder Sgl | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Power Multi | <input type="text" value="24"/> Each |
| <input type="checkbox"/> Other: Write In <input type="text"/> | <input type="text"/> Inner/ Carton/Pack |
| | <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?
 (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 | | |
| Item/Each: | 0.05 | | 1.5 | 3 | 0 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | 0 | |
| Case: | 1.95 | 10 | 7 | 4 | 280 | 24 |
| Pallet: | | | | | 0 | |

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 | 1 | | 00331722028301 | 20331722028305 |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 24 | | 20331722028305 | |
| <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#

ADD'L STORAGE INFORMATION

Is the Product...

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

CLASS OF TRADE RESTRICTION:

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

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

Med Guide Required

Limited Distribution Requirement

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

REMS: No
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:
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

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

Is product returnable for credit: Yes

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

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

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 <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"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></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 type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"><input type="checkbox"/> Monday<input type="checkbox"/> Tuesday<input type="checkbox"/> Wednesday<input type="checkbox"/> Thursday<input type="checkbox"/> Friday <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <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="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| Miscellaneous Notes: | |
| <input type="text"/> | |
| | ADDITIONAL INFORMATION |
| | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |