



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

Version 2021 Introduction Type: New Item Final Version Date:

PRODUCT INFORMATION	SPECIAL HANDLING AND STORAGE REQUIREMENTS*
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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?

e. Shelf life: **Protect product (unit of sale) from light?**

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

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
<p>The product is a legend device? <input type="text" value="No"/></p> <p>if yes, enter class # <input type="text"/></p> <p>a product kit? <input type="text" value="No"/></p> <p>if yes, list NDCs of component parts reverse numbered? <input type="text"/></p> <p>co-licensed? <input type="text" value="No"/></p> <p>latex-free? <input type="text" value="Yes"/></p> <p>preservative-free? <input type="text" value="Yes"/></p> <p>correctional institution block? <input type="text" value="No"/></p> <p>opioid? <input type="text" value="Yes"/></p> <p>Cannabinoid? <input type="text" value="No"/></p> <p>If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/></p> <p>If Unit Dose, indicate NDC here: <input type="text"/></p>	<p>Is the Product... Direct-Ship Only <input type="text"/></p> <p>Is the Product... Neither <input type="text"/></p> <p>Orphan Drug Status <input type="text"/></p> <p>FDA Approval Status <input type="text"/></p> <p>Allergens Present</p> <p><input type="text" value="Dye, Corn, Alcohol, Animal"/></p> <p>Country of Origin <input type="text" value="USA"/></p> <p>Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/></p>
	<p>Size: <input type="text" value="500 ct"/></p> <p>Strength: <input type="text" value="10 mg/325 mg"/></p> <p>Dosage Form: <input type="text" value="Tablet"/></p> <p>Product Shape: <input type="text" value="Capsule"/></p> <p>Product Color: <input type="text" value="White to off-white"/></p> <p>Product Imprint: <input type="text" value="Debossed with T 194 on one side and plain on other side"/></p>

ORDER INFORMATION

<p>Unit of Sale</p> <p><input checked="" type="checkbox"/> Bottle</p> <p><input type="checkbox"/> Box/Carton</p> <p><input type="checkbox"/> Ampule</p> <p><input type="checkbox"/> Glass</p> <p><input type="checkbox"/> Tube</p> <p><input type="checkbox"/> Vial Liquid Sgl</p> <p><input type="checkbox"/> Vial Liquid Multi</p> <p><input type="checkbox"/> Vial Powder Sgl</p> <p><input type="checkbox"/> Vial Powder Multi</p> <p><input type="checkbox"/> Other: Write In <input type="text"/></p>	<p>What is the NDC selling unit?</p> <p><input type="text" value="1 Bottle of 500 Tablets"/></p> <p>(Write-in, e.g. 1 Box of 10 Vials)</p> <p>Minimum order quantity? <input type="text" value="Yes"/></p> <p>If Yes, how many of which package type?</p> <p><input type="text" value="12"/> Each</p> <p><input type="text"/> Inner/ Carton/ Pack</p> <p><input type="text"/> Case</p>
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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

<p>Rec. sell unit to customer? <input type="text"/></p> <p>(Write-in, e.g. 1 Vial)</p>	<p>Rx billing unit to pharmacy:</p> <p><input type="text"/> Each</p> <p><input type="text"/> Gram</p> <p><input type="text"/> Milliliter</p>
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DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

Is product exempt from DSCSA?

GLN:

GCP:

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exemption/exemption for product?

If yes, attach documentation from FDA.

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:	0.58	3.1	3.1	5.56	53.43	1
Box/Carton/Bundle/ Inner Pack:						
Case:	7.4	13	9.8	6.5	828.1	12
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	1		00331722951050	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		10331722951057	
<input type="checkbox"/> Pallet				

COST INFORMATION

<p>Regular Cost <input type="text"/></p> <p>Invoice Cost (WAC) (\$) <input type="text" value="\$100.70"/></p> <p>As of date: <input type="text" value="3/14/2019"/></p>	<p>WHOLESALE USE ONLY:</p> <p>Vendor #: <input type="text"/></p> <p>Whsl. Code #: <input type="text"/></p> <p>Fineline Code: <input type="text"/></p>
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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p style="margin-top: 5px;">Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p style="margin-top: 5px;">Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, is it managed with a pharmacy registry? <input type="checkbox"/> No Website URL: <input type="text" value="https://opioidanalgesicrems.com/home.html"/></p> <p>Med Guide Required <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> Yes</p> <p>REMS Program Manager Name: <input type="text" value="Prathima Arrabally"/> Phone: <input type="text" value="(631) 881-4614 Ext. 1412"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; margin: 0;">RETURN INSTRUCTIONS</p> <p>Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> <p>DEA Form 222 or its electronic equivalent is required for all returns in all states.</p> </div>	<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
<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						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No Controlled Substance Code <input type="text" value="9143"/></p> <p>Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text" value="2"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<p>*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.</p>							



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

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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"/>	Purchase order daily receipt cut off time by supplier 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"/>	Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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 Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>