



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

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																										
<b>Company Name:</b> <input type="text" value="Camber Pharmaceuticals, Inc."/> <b>Application:</b> <input type="text" value="ANDA"/> <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="212133"/> <b>Medical Device Class, if applicable:</b> <input type="text"/> <b>DUNS:</b> <input type="text" value="11-856-3719"/> <b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Hydromorphone Hydrochloride Extended-Release Tablets 8 mg"/> <b>Selling Unit NDC:</b> <input type="text" value="31722-119-01"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="331722119016"/> <b>UDI</b> <input type="text"/> <b>CVX Code:</b> <input type="text"/> <b>MVX Code:</b> <input type="text"/> <b>Description:</b> <input type="text" value="Hydromorphone Hydrochloride Extended-Release Tablets 8 mg"/> <b>Active Ingredient(s):</b> <input type="text" value="Hydromorphone hydrochloride"/> <b>URL for Additional Product Information:</b> <input type="text" value="www.camberpharma.com"/> <b>Address:</b> <input type="text" value="800 Centennial Ave, Suite 1"/> <b>Address 2:</b> <input type="text"/> <b>City:</b> <input type="text" value="Piscataway"/> <b>State:</b> <input type="text" value="NJ"/> <b>Zip:</b> <input type="text" value="08854"/> <b>Key Contact:</b> <input type="text" value="Customer Service"/> <b>Email:</b> <input type="text" value="customerservice@camberpharma.com"/> <b>Phone Number:</b> <input type="text" value="1-866-827-3647"/> <b>Fax:</b> <input type="text" value="732-562-8788"/> <b>Product Therapeutic Classification:</b> <input type="text" value="Opioid agonist"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b> Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>																										
<b>Address:</b> <input type="text" value="800 Centennial Ave, Suite 1"/> <b>Address 2:</b> <input type="text"/> <b>City:</b> <input type="text" value="Piscataway"/> <b>State:</b> <input type="text" value="NJ"/> <b>Zip:</b> <input type="text" value="08854"/> <b>Key Contact:</b> <input type="text" value="Customer Service"/> <b>Email:</b> <input type="text" value="customerservice@camberpharma.com"/> <b>Phone Number:</b> <input type="text" value="1-866-827-3647"/> <b>Fax:</b> <input type="text" value="732-562-8788"/> <b>Product Therapeutic Classification:</b> <input type="text" value="Opioid agonist"/>		<b>b. Contact for temperature excursion questions:</b> <b>Name:</b> <input type="text" value="Soma Raju"/> <b>Number:</b> <input type="text" value="732-529-0423"/> <b>Group E-mail:</b> <input type="text" value="somaraju@heterousa.com"/>																										
<b>Additional Product Information</b>		<b>c. Special regulations for product in any states?</b> <input type="text" value="*Yes"/> Special returns requirements for this product? <input type="text" value="*Yes"/>																										
<b>PRODUCT DESCRIPTION INFORMATION</b>		<b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/> <b>Protect product (unit of sale) from light?</b> <input type="text" value="No"/> <b>e. Shelf life:</b> <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																										
The product is a legend device? <input type="text" value="No"/> if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="Yes"/> correctional institution block? <input type="text" value="No"/> opioid? <input type="text" value="Yes"/> Cannabinoid? <input type="text" value="No"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> If Unit Dose, indicate NDC here: <input type="text"/>		<b>ORDER INFORMATION</b> <b>Unit of Sale</b> <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In <input type="text"/> <b>What is the NDC selling unit?</b> <input type="text" value="1 Bottle of 100 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials) <b>Minimum order quantity?</b> <input type="text" value="Yes"/>																										
<b>Is the Product... Direct-Ship Only</b> <input type="text"/> <b>Is the Product... Neither</b> <input type="text"/> <b>Orphan Drug Status</b> <input type="text"/> <b>FDA Approval Status</b> <input type="text"/> <b>Allergens Present</b> <input type="text" value="Corn, Alcohol"/> <b>Country of Origin</b> <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>		<b>Size:</b> <input type="text" value="100 ct"/> <b>Strength:</b> <input type="text" value="8 mg"/> <b>Dosage Form:</b> <input type="text" value="Film coated tablet"/> <b>Product Shape:</b> <input type="text" value="Round, biconvex"/> <b>Product Color:</b> <input type="text" value="Light pink to pink"/> <b>Product Imprint:</b> <input type="text" value="Printed with '266' in black ink on one side of the tablet"/>																										
FOR GENERIC DRUG PRODUCTS																												
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Exalgo"/>																												
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																												
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/> <b>Is product exempt from DSCSA?</b> <input type="text" value="No"/> <b>GLN:</b> <input type="text" value="0860000397957"/> <b>If yes, select exemption:</b> <input type="text"/> <b>Other exemption - Write in:</b> <input type="text"/> <b>GCP:</b> <input type="text"/> <b>Is product repackaged?</b> <input type="text" value="No"/> <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="Yes"/> <b>Has FDA granted waiver/exemption/exemption for product?</b> <input type="text" value="No"/> <b>If yes, attach documentation from FDA.</b> <input type="text"/> <b>If yes, was original product purchased direct from mfr?</b> <input type="text"/> <b>Provide source manufacturer for repackaged product</b> <input type="text"/>																												
GTIN AND HIBCC PRODUCT INFORMATION																												
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Saleable Unit of Measure</th> <th>Saleable Quantity</th> <th>HIBCC</th> <th>GTIN-14</th> <th>Unit of Use GTIN-14</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Item/Each</td> <td><input type="text" value="1"/></td> <td><input type="text"/></td> <td><input type="text" value="00331722119016"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Case</td> <td><input type="text" value="24"/></td> <td><input type="text"/></td> <td><input type="text" value="10331722119013"/></td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Pallet</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>				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="00331722119016"/>	<input type="text"/>	<input checked="" 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="10331722119013"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																								
<b>Weight Lbs.</b> <input type="text" value="0.08"/> <b>Dimensions (US msmts.)</b> <b>Depth</b> <input type="text" value="1.84"/> <b>Width</b> <input type="text" value="1.84"/> <b>Height</b> <input type="text" value="3.23"/> <b>Volume (Cube)</b> <input type="text" value="10.86"/> <b>Saleable # Pieces</b> <input type="text" value="1"/> <b>Item/Each:</b> <input type="text"/> <b>Box/ Carton/ Bundle/ Inner Pack:</b> <input type="text"/> <b>Case:</b> <input type="text" value="1.92"/> <input type="text" value="12.3"/> <input type="text" value="8.3"/> <input type="text" value="3.8"/> <input type="text" value="387.94"/> <input type="text" value="24"/> <b>Pallet:</b> <input type="text"/>		<b>PHARMACY ORDER / BILL UNIT</b> <b>Rec. sell unit to customer?</b> <input type="text"/> (Write-in, e.g. 1 Vial) <b>Rx billing unit to pharmacy:</b> <input type="text"/> Each <input type="text"/> Gram <input type="text"/> Milliliter																										
<b>Regular Cost</b> <input type="text"/> <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$769.85"/> <b>As of date:</b> <input type="text" value="10/6/2020"/>		<b>WHOLESALE USE ONLY:</b> <b>Vendor #:</b> <input type="text"/> <b>Whsl. Code #:</b> <input type="text"/> <b>Fineline Code:</b> <input type="text"/>																										

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:

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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 &amp; 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;"> <p style="text-align: center; margin: 0;"><b>SDS Hazard Classification</b></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>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>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-top: 5px;"> <p style="text-align: center; margin: 0;"><b>Hazardous Waste Identification</b></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-top: 5px;"> <p style="text-align: center; margin: 0;"><b>REMS or REGISTRY RESTRICTIONS</b></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            Limited Distribution Requirement <input type="checkbox"/> No            Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b> <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"/>            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"/></p> <p>Comments: <input type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/>            Comments: <input type="text"/></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="9150"/></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>	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; margin: 0;"><b>RETURN INSTRUCTIONS</b></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>						
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>	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; margin: 0;"><b>MISCELLANEOUS NOTES and/or Image of Product Barcode:</b></p> <p>*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.</p> </div>						



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

Version 2021

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"/>