



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: <input type="text" value="Camber Pharmaceuticals, Inc."/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="212133"/> Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text" value="11-856-3719"/> Proprietary Name (If Applicable) and Established Name: <input type="text" value="Hydromorphone Hydrochloride Extended-Release Tablets 12 mg"/> Selling Unit NDC: <input type="text" value="31722-120-01"/> Unit of Use NDC: <input type="text"/> UPC: <input type="text" value="331722120012"/> UDI <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Hydromorphone Hydrochloride Extended-Release Tablets 12 mg"/> Active Ingredient(s): <input type="text" value="Hydromorphone hydrochloride"/> URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/> Address: <input type="text" value="800 Centennial Ave, Suite 1"/> Address 2: <input type="text"/> City: <input type="text" value="Piscataway"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08854"/> Key Contact: <input type="text" value="Customer Service"/> Email: <input type="text" value="customerservice@camberpharma.com"/> Phone Number: <input type="text" value="1-866-827-3647"/> Fax: <input type="text" value="732-562-8788"/> Product Therapeutic Classification: <input type="text" value="Opioid agonist"/>		a. Temperature – Indicate the USP temperature range for this product. 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. Contact for temperature excursion questions: Name: <input type="text" value="Soma Raju"/> Number: <input type="text" value="732-529-0423"/> Group E-mail: <input type="text" value="somaraju@heterousa.com"/> c. Special regulations for product in any states? <input type="text" value="*Yes"/> Special returns requirements for this product? <input type="text" value="*Yes"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																														
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION																																														
The product is it 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"/>		Is the Product... Direct-Ship Only <input type="text"/> Is the Product... Neither <input type="text"/> Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text" value="Corn, Alcohol"/> Country of Origin <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>																																														
		Size: <input type="text" value="100 ct"/> Strength: <input type="text" value="12 mg"/> Dosage Form: <input type="text" value="Film coated tablet"/> Product Shape: <input type="text" value="Round, biconvex"/> Product Color: <input type="text" value="Light yellow to yellow"/> Product Imprint: <input type="text" value="Printed with '267' in black ink on one side of the tablet"/>																																														
FOR GENERIC DRUG PRODUCTS																																																
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text" value="Exalgo"/>																																																
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> Is product exempt from DSCSA? <input type="text" value="No"/> GLN: <input type="text" value="0860000397957"/> If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/> GCP: <input type="text"/> Is product repackaged? <input type="text" value="No"/> Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/> Has FDA granted waiver/exemption/exemption for product? <input type="text" value="No"/> If yes, attach documentation from FDA. <input type="text"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <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="00331722120012"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Box/Case/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="10331722120019"/></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="00331722120012"/>	<input type="text"/>	<input checked="" type="checkbox"/> Box/Case/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="10331722120019"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
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PHARMACY ORDER / BILL UNIT																																																
Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="text" value="Each"/> <input type="text"/> Gram <input type="text"/> Milliliter																																																
ITEM AND PACKING INFORMATION																																																
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item/Each:</th> <th colspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2">Saleable # Pieces</th> </tr> <tr> <th></th> <th></th> <th>Depth</th> <th>Width</th> <th>Height</th> </tr> </thead> <tbody> <tr> <td></td> <td>0.10</td> <td>1.84</td> <td>1.84</td> <td>3.23</td> <td>10.86</td> <td>1</td> <td></td> </tr> <tr> <td>Box/Case/Bundle/Inner Pack:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Case:</td> <td>2.3</td> <td>12.3</td> <td>8.3</td> <td>3.8</td> <td>387.94</td> <td>24</td> <td></td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				Item/Each:	Weight Lbs.		Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces			Depth	Width	Height		0.10	1.84	1.84	3.23	10.86	1		Box/Case/Bundle/Inner Pack:								Case:	2.3	12.3	8.3	3.8	387.94	24		Pallet:							
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COST INFORMATION		WHOLESALE USE ONLY:																																														
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$1,150.61"/> As of date: <input type="text" value="10/6/2020"/>		Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <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 & 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>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-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 Limited Distribution Requirement <input type="checkbox"/> No <input type="checkbox"/> Yes Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> Yes <input type="checkbox"/> No</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>Registry: <input type="checkbox"/> No <input type="checkbox"/> Yes Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> 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"/> Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No 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 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
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<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"/> Yes <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 <input type="checkbox"/> Yes</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 <input type="checkbox"/> Yes</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No <input type="checkbox"/> Yes</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)

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"/>	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
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>