



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 16 mg"/> Selling Unit NDC: <input type="text" value="31722-121-01"/> Unit of Use NDC: <input type="text"/> UPC: <input type="text" value="331722121019"/> UDI <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Hydromorphone Hydrochloride Extended-Release Tablets 16 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 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="16 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 beige to beige"/> Product Imprint: <input type="text" value="Printed with '268' 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																																															
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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"/> <input type="text"/> 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 rowspan="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>Depth</th> <th>Width</th> <th>Height</th> </tr> </thead> <tbody> <tr> <td></td> <td>0.11</td> <td>1.84</td> <td>1.84</td> <td>3.23</td> <td>10.86</td> <td>1</td> </tr> <tr> <td>Box/Case/Bundle/Inner Pack:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Case:</td> <td>2.7</td> <td>12.3</td> <td>8.3</td> <td>3.8</td> <td>387.94</td> <td>24</td> </tr> <tr> <td>Pallet:</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		0.11	1.84	1.84	3.23	10.86	1	Box/Case/Bundle/Inner Pack:							Case:	2.7	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="\$1,534.14"/> 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 _____</p> <p>b. Proper Shipping Name _____</p> <p>c. DOT Hazard Class _____</p> <p>d. Packing Group _____</p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</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 _____</p> <p>b. Proper Shipping Name _____</p> <p>c. DOT Hazard Class _____</p> <p>d. Packing Group _____</p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</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: _____</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# _____</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: 1px solid black;"> <tr> <td><input checked="" type="checkbox"/> Organic</td> <td><input type="checkbox"/> Corrosive</td> </tr> <tr> <td><input type="checkbox"/> Inorganic</td> <td><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td><input type="checkbox"/> Steroid/Androgen</td> <td><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No NFPA Storage Level: _____</p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: _____</p>	<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						
Hazardous Waste Identification							
EPA Hazardous Waste Code: _____ Waste Characteristics: _____							
REMS or REGISTRY RESTRICTIONS							
<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: 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?) _____</p> <p>REMS: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>REMS Program Manager Name: Prathima Arrabally Phone: (631) 881-4614 Ext. 1412 Supplier Manages REMS registry exclusively: _____ Wholesale distributor support: _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ Comments: _____</p> <p>Registry: <input type="checkbox"/> No <input type="checkbox"/> Yes Registry Program Contact Name: _____ Phone: _____ Comments: _____</p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: 1-866-827-3647</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No URL/Link to returns policy: 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? _____</p> <p>DEA Form 222 or its electronic equivalent is required for all returns in all states.</p>							
ADD'L STORAGE INFORMATION							
<p>Is the Product... Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No Controlled Substance Code: 9150 Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> No ARCOS Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate which: _____ Schedule No. 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 <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: _____</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 Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>