



# 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="201807"/> <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="Indomethacin Extended-release Capsules, USP 75 mg"/> <b>Selling Unit NDC:</b> <input type="text" value="31722-565-01"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="331722565011"/> <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="Indomethacin Extended-release Capsules, USP 75 mg"/> <b>Active Ingredient(s):</b> <input type="text" value="Indomethacin, USP"/> <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="Non-steroidal anti-inflammatory indole derivative drug (NSAID)"/>		<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>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>c. Special regulations for product in any states?</b> <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> <b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/> <b>e. Shelf life:</b> <input type="text" value="No"/> <input type="text" value="24"/> <input type="text" value="24"/> <b>Months</b> Protect product (unit of sale) from light? <input type="text" value="No"/> Initial shelf life at launch (if different): <input type="text"/> <b>Months</b>																																							
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="No"/> 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>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, Animal Products, Sugar, Wheat"/> <b>Country of Origin</b> <input type="text" value="India"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>																																							
<b>Size:</b> <input type="text" value="100 ct"/> <b>Strength:</b> <input type="text" value="75 mg"/> <b>Dosage Form:</b> <input type="text" value="Hard gelatin capsule"/> <b>Product Shape:</b> <input type="text" value="Capsule"/> <b>Product Color:</b> <input type="text" value="Dark yellow cap and clear, transparent body Imprinted with 'H' on cap and '105' on body"/> <b>Product Imprint:</b> <input type="text"/>		<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 Capsules"/> (Write-in, e.g. 1 Box of 10 Vials) <b>Minimum order quantity?</b> <input type="text" value="Yes"/> <b>If Yes, how many of which package type?</b> <input type="text" value="24"/> Each <input type="text"/> Inner/ Carton/ Pack <input type="text"/> Case																																							
FOR GENERIC DRUG PRODUCTS																																									
<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable <b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="N/A - This product is the Reference Standard"/>																																									
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="0331722498975"/> <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/exception/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="00331722565011"/></td> <td><input type="text"/></td> </tr> <tr> <td><input 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="20331722565015"/></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="00331722565011"/>	<input type="text"/>	<input 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="20331722565015"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>													
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ORDER INFORMATION																																									
<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																																									
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COST INFORMATION		WHOLESALE USE ONLY:																																							
<b>Regular Cost</b> <input type="text"/> <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$125.00"/> <b>As of date:</b> <input type="text" value="4/3/2017"/>		<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:



Version 2021

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?

- No (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?  No
- 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	
<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
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="checkbox"/> No
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No
	<input type="text"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<input type="checkbox"/> No
If Yes, is it managed with a pharmacy registry? Website URL:	<input type="text"/>
Med Guide Required	<input type="checkbox"/> No
Limited Distribution Requirement	<input type="text"/>
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	<input type="checkbox"/> No
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/>
Wholesale distributor support:	<input type="checkbox"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
Phone:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
<b>Registry:</b>	<input type="checkbox"/> No
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	1-866-827-3647
Is product returnable for credit:	<input type="checkbox"/> Yes
URL/Link to returns policy:	<input type="text"/>
	contact - customerservice@camberpharma.com
Special regulations or returns requirements for this product in certain states?	<input type="checkbox"/> No
If so, which states? Other requirements? Comments?	<input type="text"/>

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



# 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"/>