

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

| Version 2021   |                             |                     |                            |               |                                 | Introduction Type:   | New Item                          |                                | x Final Version                      |                      |                         | Date:         | 6/23/         | /2024      |
|--|-----------------------------|---------------------|----------------------------|---------------|---------------------------------|--|-----------------------------------|--------------------------------|--------------------------------------|----------------------|-------------------------|---------------|---------------|------------|
|  |                             |                     | PRODUCT INFORMA            | TION          |                                 |  |                                   |                                | SPECIAL HAN                          | DLING AND STOR       | AGE REQUI               | REMENTS*      |               |            |
| Company Name: Camber Pharmaceuticals, Inc.               |                             |                     |                            | Application:  | ANDA                            | a. Temperature - Indicate the USP temperature range for this produ |                                   |                                |                                      |                      |                         |               |               |            |
| Application Number for NDA/AN                            | NDA/BLA (drug); PN          | IA/510(k)(med devic | e):                        | 21:           | 2378                            |  |                                   |                                | Temperature Range                    | Controlled Room -    |                         | and 25 C (68  | ° – 77° F)    |            |
| Medical Device Class, if applica                         |                             |                     |                            |               |                                 |  |                                   | 1                              | · -                                  |                      |                         |               |               |            |
| DUNS:  | 11-856-3719                 |                     |                            |               |                                 |  |                                   |                                | Other Temperature Range F            | Requirement          |                         |               |               |            |
| Proprietary Name (If Applicable)                         | and Established Na          | me: Baclof          | en Tablets, USP 20 mg      |               |                                 |  |                                   | I                              | (write in)                           |                      |                         |               |               |            |
| Selling Unit NDC:  | 31722-999-10                |                     | Unit of Use NDC:           |               |                                 |  | 722999106                         |                                | Notes                                |                      |                         |               |               |            |
| UDI  |                             |                     | CVX Code:                  |               |                                 | MVX Code:  |                                   | <u> </u>                       |                                      |                      |                         |               |               |            |
| Description:   | Baclofen Tablets,           | USP 20 mg           |                            |               |                                 |  |                                   | Ţ                              | Is this product to be shipped        | d to customers on ic | e?                      |               | No            | 1          |
|  |                             |                     |                            |               |                                 |  |                                   |                                | Is this product to be shipped        |                      |                         |               | No            | 1          |
| Active Ingredient(s):                                    |                             | Baclofen, USP       |                            |               |                                 |  |                                   |                                |                                      |                      |                         |               |               |            |
|  |                             |                     |                            |               |                                 |  |                                   | b. Contact for                 | temperature excursion que            | estions:             |                         |               |               |            |
| URL for Additional Product Inform                        |                             | www.camberpharma    | a.com                      |               |                                 |  |                                   |                                | Name:                                |                      | Soma Raju               |               |               |            |
| Address:   | 800 Centennial Av           | e, Suite 1          |                            |               | State:                          | Address 2:   | 00054                             |                                | Number:                              |                      | 732-529-042             |               |               |            |
| City:<br>Key Contact:                                    | Piscataway Customer Service |                     |                            |               | Email:                          | customerservice@carr   | o: 08854                          |                                | Group E-mail:                        |                      | somaraju@h              | ieterousa.com | <u> </u>      |            |
| Phone Number:  | 1-866-827-3647              |                     |                            |               | Fax:                            | 732-562-8788   | iborpriama.com                    | c Special reg                  | ulations for product in any          | states?              |                         |               | No            | 1          |
| Product Therapeutic Classification                       |                             | Muscle relaxant and | d antispastic              |               |                                 |  |                                   | o. oposiai iog                 | Special returns requirement          |                      |                         |               | No            | 1          |
| Troduct Therapeutic Glassification                       | JII.                        | Maddio Tolaxani and | анторионо                  |               | J                               |  |                                   |                                | opeoidi returno requirement          | s for this product:  |                         |               | 140           |            |
|  | ADDITIO                     | DNAL PRODUCT IN     | FORMATION                  |               |                                 | PRODUCT DESC   | RIPTION INFORMATION               | d. Store produ                 | uct (unit of sale) upright?          |                      |                         |               | No            | 1          |
| The product is 2   |                             |                     | Is the Product             | Direct-Ship C | Inly                            |  |                                   |                                |                                      | la) fuam limbto      |                         |               | No            | 1          |
| The product is? a legend device?                         |                             | No                  | Is the Product             | Neither       | Tilly                           |  | 1000 ct                           | e. Shelf life:                 | Protect product (unit of sa          | ile) from light?     |                         |               | 24            | Months     |
| if yes, enter class #                                    |                             | INU                 | Orphan Drug Status         | Telater       |                                 | Size:  | 1000 Ct                           | e. Sileli ille.                | Initial shelf life at launch (       | if different):       |                         |               | 24            | Months     |
| a product kit?   |                             | No                  | o.p.ia D. ag otatao        |               |                                 |  | 20 mg                             |                                | maar onon mo at laanon (             |                      |                         |               |               | 1          |
| if yes, list NDCs of                                     |                             |                     | FDA Approval Status        |               |                                 | Strength:  | - 3                               |                                |                                      | ORDER INFORM         | IATION                  |               |               |            |
| component parts  |                             |                     |                            |               |                                 | Dosage Form:   | Tablet                            |                                |                                      |                      |                         |               |               |            |
| reverse numbered?  |                             | No                  |                            |               |                                 | Dosage i oiii.   |                                   |                                | Unit of Sale                         |                      | What is the             |               | unit?         |            |
| co-licensed?   |                             | No                  | Allergens Present          |               |                                 |  |                                   |                                | x Bottle                             |                      | 1 Bottle of 1           |               |               |            |
| latex-free?  |                             | Yes                 | Dairy,                     | Lactose       |                                 | Product Shape:   | Round, flat, bevel edged          |                                | Box/Carton                           |                      | (Write-in, e.           | g. 1 Box of 1 | 0 Vials)      |            |
| preservative-free?                                       |                             | Yes                 |                            |               |                                 | •  | 1411 12 2 22 1 12                 |                                | Ampule                               |                      |                         |               | _             |            |
| correctional institution block?                          |                             | No                  |                            |               |                                 | Product Color:   | White to off-white                |                                | Glass                                |                      | Minimum or              | der quantity  | ?             | Yes        |
| opioid? Cannabinoid?                                     |                             | No                  | Country of Origin          | USA           |                                 |  | Debossed with 'I 115' on one side |                                | Tube                                 |                      |                         |               |               |            |
| If Unit Dose, is item bar coded to                       | unit dose for               | No                  | Country of Origin          | USA           |                                 | Product Imprint:   | and scored on the other side      |                                | Vial Liquid Sgl<br>Vial Liquid Multi |                      | If Yes how              | many of whi   | ch package t  | tyne?      |
| hospital scanning?                                       | unit dose for               |                     | Is this product covered to | inder the     |                                 |  |                                   |                                | Vial Powder Sql                      |                      |                         | Each          | cii package i | type:      |
| If Unit Dose, indicate NDC here:                         |                             |                     | Trade Agreements Act (     |               | Yes                             |  |                                   |                                | Vial Powder Multi                    |                      |                         | Inner/Cartor  | /Pack         |            |
|  |                             |                     |                            | ,             |                                 |  |                                   |                                | Other: Write In                      |                      |                         | Case          |               |            |
|  |                             |                     | FOR GENERIC DRUG PR        | ODUCTS        |                                 |  |                                   |                                |                                      |                      |                         | 4             |               |            |
|  |                             |                     |                            |               |                                 |  |                                   |                                |                                      |                      |                         |               |               |            |
|  |                             |                     |                            |               | Au                              |  | uthorized Generic, other          |                                | PH                                   | ARMACY ORDER         | / BILL UNIT             |               |               |            |
| I. Orange Book Rating:                                   | AB                          |                     |                            |               |                                 | sect   | ion fields are not applicable     | Rec. sell unit                 | to customer?                         |                      | Rx billing u            | nit to pharm  | acy:          |            |
| II. Generic Equivalent to What Bra                       | and?:                       | Lioresal            |                            |               |                                 |  |                                   |                                |                                      | 1                    |                         | Each          | •             |            |
|  |                             |                     |                            |               |                                 |  |                                   | (Write-in, e.g.                | 1 Vial)                              | -                    |                         | Gram          |               |            |
|  |                             | DRUG SUPPL          | Y CHAIN SECURITY ACT       | (DSCSA) INFOR | MATION                          |  |                                   |                                |                                      |                      |                         | Milliliter    |               |            |
|  |                             | _                   |                            | _             |                                 |  |                                   |                                |                                      |                      |                         |               |               |            |
| Does supplier meet DSCSA defin                           |                             | er?                 | Yes<br>No                  | _             | GLN:                            | 0331722498975  |                                   |                                | IIEN                                 | I AND PACKING II     | IFORMATIO               | N .           |               |            |
| Is product exempt from DSCSA?                            |                             |                     | INO                        |               |                                 |  |                                   |                                |                                      |                      |                         |               |               |            |
| If yes, select exemption:                                |                             |                     |                            |               | GCP:                            |  |                                   |                                | Weight Lbs.                          |                      | ons (US msn             | •             | Volume        | Saleable # |
| Other exemption - Write in:                              |                             |                     | No                         |               | W                               | dainal anadoret corret   |                                   | 140 mg/F 1                     |                                      | Depth                | Width                   | Height        | (Cube)        | Pieces     |
| Is product repackaged? Is product sold by manufacturer's | e avalueiva dietribu        | tor?                | Yes                        | _             | If yes, was or<br>direct from m | iginal product purchase  | eu .                              | Item/Each:                     | 1.05                                 | 3.5                  | 3.5                     | 6.5           | 79.63         | 1          |
| Has FDA granted waiver/exception                         |                             |                     | No                         | <del> </del>  |                                 | ir r<br>ce manufacturer for rep                                    | ackaged product                   | Box/Carton/B                   | undle/                               |                      |                         |               |               |            |
| If yes, attach documentation fro                         |                             | Judot.              | 110                        |               | Trovide South                   | oc manaradarer for rep   | ackagea product                   | Inner Pack:                    | undic/                               |                      |                         |               |               |            |
| . , ,  |                             |                     |                            |               |                                 |  |                                   | Case:                          | 10.05                                | 44.5                 | 40.75                   | 7.5           | 4400.00       | 40         |
|  |                             | GTI                 | N AND HIBCC PRODUCT I      | NFORMATION    |                                 |  |                                   |                                | 13.05                                | 14.5                 | 10.75                   | 7.5           | 1169.06       | 12         |
|  |                             |                     |                            |               |                                 |  |                                   | Pallet:                        |                                      |                      |                         |               |               |            |
|  |                             |                     | HIBCC                      |               |                                 | N-14   | Unit of Use GTIN-14               |                                |                                      |                      |                         |               |               |            |
| Saleable Unit of Measure                                 | S                           | aleable Quantity    | TIIDOO                     |               | 003                             | 331722999106   |                                   |                                |                                      |                      |                         |               |               |            |
| X Item/Each  | S                           | aleable Quantity    | Tilbee                     |               | -                               |  |                                   |                                |                                      |                      |                         |               |               | Υ:         |
| X Item/Each Box/Carton/Bundle/Inner Pack                 | S                           | 1                   | THECO                      |               |                                 |  |                                   |                                | COST INFORMATION                     |                      |                         | WHOLESAL      | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | S                           |                     | TIBOC                      |               | 103                             | 331722999103   |                                   | Bendar Co. 1                   | COST INFORMATION                     |                      |                         | WHOLESAL      | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack                 | s                           | 1                   | Tilbec                     |               | 103                             | 331722999103   |                                   | Regular Cost                   |                                      | #00.00               | Vendor #:               |               | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | s                           | 1                   |                            |               | 103                             | 331722999103   |                                   | Regular Cost<br>Invoice Cost ( |                                      | \$80.00              | Vendor #:<br>Whsl. Code | #:            | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | s                           | 1                   | Tilboo                     |               | 103                             | 331722999103   |                                   | Invoice Cost (                 |                                      | \$80.00              | Vendor #:               | #:            | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | s                           | 1                   | Tilboo                     |               | 103                             | 331722999103   |                                   |                                | WAC) (\$)                            | \$80.00              | Vendor #:<br>Whsl. Code | #:            | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | s                           | 1                   |                            |               | 103                             | 331722999103   |                                   | Invoice Cost (                 | WAC) (\$)                            | \$80.00              | Vendor #:<br>Whsl. Code | #:            | ER USE ONL    |            |
| X Item/Each Box/Carton/Bundle/Inner Pack X Case          | s                           | 1                   |                            | ATA SHEET (SC |                                 |  | ERT, LABEL AND PHOTO OF I         | Invoice Cost (                 | WAC) (\$)<br>7/1/2021                | \$80.00              | Vendor #:<br>Whsl. Code | #:            | ER USE ONL    |            |



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

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HA   | ZARD CLASSIFICATION and TRANSPORTATION  |  |  |  |  |  |
|---|---|--|--|--|--|--|
| Is this product (check all that apply): a. Cytotoxic?  No   | SDS Hazard Classification   |  |  |  |  |  |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No   | x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard  |  |  |  |  |  |
| c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?   | Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:   |  |  |  |  |  |
| 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  | Is the product a NIOSH hazardous drug?  If yes, indicate which:   |  |  |  |  |  |
| c. DOT Hazard Class d. Packing Group  | Hazardous Waste Identification  |  |  |  |  |  |
| e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No  | EPA Hazardous Waste Code: Waste Characteristics   |  |  |  |  |  |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number  | REMS or REGISTRY RESTRICTIONS   |  |  |  |  |  |
| b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?  | Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:   |  |  |  |  |  |
| Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo   | Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)   |  |  |  |  |  |
| 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) | REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  No  Phone:  DEA #:  NCPDP#:  NPI #: |  |  |  |  |  |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#  | Comments  |  |  |  |  |  |
| ADD'L STORAGE INFORMATION   | Registry:  Registry Program Contact Name:  Comments  No  Phone:   |  |  |  |  |  |
| Is the Product  |   |  |  |  |  |  |
| Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  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:                           | RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  | URL/Link to returns policy:  contact - customerservice@camberpharma.com   |  |  |  |  |  |
| Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No   | Special regulations or returns requirements for this product in certain states?   |  |  |  |  |  |
| Restricted from US territories? (explain in comments)  No  Comments:  | If so, which states? Other requirements? Comments?  |  |  |  |  |  |
| MISCELLANE  | DUS 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 S  | nip Product             | Standard Order Receipt and Processing  |
|---|-------------------------|--|
| Purchase orders may be accepted by: a. EDI  |                         | Purchase order daily receipt cut off time by supplier Cut off time:  |
| b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:  | per:                    | Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:   |
| Expedited Freight Charges or Other Designa  | ed Drop Ship Fees:      | Overnight and Priority Overnight PO Processing   |
| Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:   |                         | Overnight receipt available:  PO Receipt cut off time:   |
| Drop Ship miscellaneous fees billed:  Comments:   |                         | Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday   |
|   |                         | Priority Overnight receipt available:  |
| Class of Trade Restriction  |                         | PO Receipt Cut off time:   |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: | s and physician offices | Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:   |
| Other Data Information Required to F  | rocess PO:              | Return Instructions  |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  |                         | Contact # if product is received damaged:  Is product returnable for credit:  URL/Link to returns policy:  Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments? |
| Miscellaneous Notes:  |                         |  |
|   |                         |  |
|   |                         | ADDITIONAL INFORMATION   |
|   |                         | Is product order for scheduled patient procedure? Is product order for restocking purposes?  |