

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

| Version 2021   |                    |                         |                             |                 |                 | Introduction Typ      | De: New Item  |                           | x Final Version                      |                     |                                 | Date:            | 11/8/      | /2023      |
|--|--------------------|-------------------------|-----------------------------|-----------------|-----------------|-----------------------|---|---------------------------|--------------------------------------|---------------------|---------------------------------|------------------|------------|------------|
|  |                    |                         | PRODUCT INFORMA             | TION            |                 |                       |   |                           | SPECIAL HAN                          | DLING AND STOF      | AGE REQUIF                      | REMENTS*         |            |            |
| Company Name:  | Camber Pharmac     | euticals, Inc.          |                             |                 |                 | Application           | n: ANDA   | a. Temperatur             | e - Indicate the USP tempe           | rature range for t  | his product.                    |                  |            |            |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216800 |                    |                         | 6800                        |                 |                 |                       | Temperature Range   Controlled Room – between 20 and 25 C (68° – 77° F) |                           |                                      |                     |                                 |                  |            |            |
| Medical Device Class, if applicable:                                       |                    |                         |                             |                 |                 |                       |   |                           |                                      |                     |                                 |                  |            |            |
| DUNS:  | 11-856-3719        |                         |                             |                 | 1               |                       |   |                           | Other Temperature Range F            | Requirement         |                                 |                  |            |            |
| Proprietary Name (If Applicable) as  | nd Established Na  | ame: Bupro              | pion Hydrochloride Extended | I-Release Table | ts, USP (SR) 10 | 00 mg                 |   |                           | (write in)                           | ·                   |                                 |                  |            |            |
| Selling Unit NDC:  | 31722-066-05       |                         | Unit of Use NDC:            |                 |                 |                       | 31722066051   |                           | Notes                                |                     |                                 |                  |            |            |
| UDI  |                    |                         | CVX Code:                   |                 |                 | MVX Code:             |   |                           |                                      |                     |                                 |                  |            |            |
| Description:   | Bupropion Hydroc   | hloride Extended-Re     | elease Tablets, USP (SR) 10 | ) ma            |                 |                       |   |                           | Is this product to be shipped        | I to customers on i | ce?                             |                  | No         | 1          |
|  | ., ., . , ,        |                         | ,,,,,                       |                 |                 |                       |   |                           | Is this product to be shipped        |                     |                                 |                  | No         |            |
| Active Ingredient(s):  |                    | Bupropion Hydroch       | loride                      |                 |                 |                       |   |                           |                                      |                     | •                               |                  |            | -          |
|  |                    |                         |                             |                 |                 |                       | b. Contact for  | temperature excursion que | estions:                             |                     |                                 |                  |            |            |
| URL for Additional Product Inform  |                    | www.camberpharma        |                             |                 |                 |                       |   |                           | Name:                                |                     | Soma Raju                       |                  |            |            |
| Address:   |                    | Ave (and) 800 Center    | nnial Ave, Suite 1          |                 |                 | Address 2:            |   |                           | Number:                              |                     | 732-529-042                     |                  |            |            |
| City:  | Piscataway         |                         |                             |                 | State:          |                       | Zip: 08854  |                           | Group E-mail: somaraju@heterousa.com |                     |                                 |                  | <u>n</u>   |            |
| Key Contact:   |                    | Customer Service Email: |                             |                 |                 | customerservice@c     | amberpharma.com   | <u> </u>                  |                                      |                     |                                 | 1                |            |            |
| Phone Number:  | 1-866-827-3647     |                         |                             |                 | Fax:            | 732-562-8788          |   | c. Special reg            | ulations for product in any          |                     |                                 |                  | No         | -          |
| Product Therapeutic Classification   | 1:                 | Aminoketone Antid       | epressant (NDRI)            |                 |                 |                       |   |                           | Special returns requirement          | s for this product? |                                 |                  | No         |            |
|  |                    |                         |                             |                 |                 |                       |   | _                         |                                      |                     |                                 |                  |            | -          |
|  | ADDITI             | ONAL PRODUCT IN         | IFORMATION                  |                 |                 | PRODUCT DE            | SCRIPTION INFORMATION   | d. Store produ            | uct (unit of sale) upright?          |                     |                                 |                  | No         |            |
| The product is?  |                    |                         | Is the Product              | Direct-Ship 0   | Only            |                       |   |                           | Protect product (unit of sa          | le) from light?     |                                 |                  | No         |            |
| a legend device?   |                    | No                      | Is the Product              | Neither         |                 | Size:                 | 500 ct  | e. Shelf life:            |                                      |                     |                                 |                  | 24         | Months     |
| if yes, enter class #  |                    |                         | Orphan Drug Status          |                 |                 | 0.20.                 |   |                           | Initial shelf life at launch (i      | f different):       |                                 |                  |            | Months     |
| a product kit?   |                    | No                      |                             |                 |                 | Strength:             | 100 mg  |                           |                                      |                     |                                 |                  |            |            |
| if yes, list NDCs of   |                    |                         | FDA Approval Status         |                 |                 |                       |   |                           |                                      | ORDER INFORM        | IATION                          |                  |            |            |
| component parts  |                    |                         |                             |                 |                 | Dosage Form:          | Film coated tablet  |                           | H-2                                  |                     | \A/h-a4 in 4h-a                 | NDC asilias      |            |            |
| reverse numbered?  |                    | No                      | Allanana Duacant            |                 |                 |                       |   |                           | Unit of Sale                         |                     | What is the                     |                  | unit?      |            |
| co-licensed?<br>latex-free?  |                    | No<br>Yes               | Allergens Present           |                 |                 |                       | Round, biconvex, bevel  |                           | Bottle Box/Carton                    |                     | 1 Bottle of 50<br>(Write-in, e. |                  | O Violo)   |            |
| preservative-free?   |                    | Yes                     |                             | ye              |                 | Product Shape         | edged   |                           | Ampule                               |                     | (vviite-iii, e.                 | y. 1 box 01 1    | U Viais)   |            |
| correctional institution block?  |                    | No                      |                             |                 |                 |                       | Pod   |                           | Glass                                |                     | Minimum or                      | der auantity     | 12         | Yes        |
| opioid?  |                    | No                      |                             |                 |                 | Product Color:        | Titod   |                           | Tube                                 |                     | Million Or                      | uci quainity     | •          | 103        |
| Cannabinoid?   |                    | No                      | Country of Origin           | India           |                 |                       | 'V1 48' on one side and   |                           | Vial Liquid Sgl                      |                     |                                 |                  |            |            |
| If Unit Dose, is item bar coded to u                                       | nit dose for       | 1.14                    | ,                           |                 |                 | Product Imprin        | t: plain on other side  |                           | Vial Liquid Multi                    |                     | If Yes, how                     | many of whi      | ch package | type?      |
| hospital scanning?   |                    |                         | Is this product covered u   | inder the       |                 |                       |   |                           | Vial Powder Sql                      |                     |                                 | Each             |            | ••         |
| If Unit Dose, indicate NDC here:   |                    |                         | Trade Agreements Act (      | ГАА)?           | No              |                       |   |                           | Vial Power Multi                     |                     |                                 | Inner/Carton     | /Pack      |            |
|  |                    |                         |                             |                 |                 |                       |   |                           | Other: Write In                      |                     |                                 | Case             |            |            |
|  |                    |                         | FOR GENERIC DRUG PR         | ODUCTS          |                 |                       |   |                           |                                      |                     |                                 |                  |            |            |
|  |                    |                         |                             |                 |                 |                       |   |                           |                                      |                     | _                               |                  |            |            |
|  |                    |                         |                             |                 | Au              |                       | If Authorized Generic, other  |                           | PH                                   | ARMACY ORDER        | / BILL UNIT                     |                  |            |            |
| I. Orange Book Rating:   | AB1                |                         |                             |                 |                 | S                     | ection fields are not applicable  | Rec. sell unit            | to customer?                         |                     | Rx billing ur                   | nit to pharm     | acy:       |            |
| II. Generic Equivalent to What Bran  | nd?:               | Wellbutrin® SR          |                             |                 |                 |                       |   |                           |                                      |                     |                                 | Each             | -          |            |
|  |                    |                         |                             |                 |                 |                       |   | (Write-in, e.g.           | 1 Vial)                              | •                   |                                 | Gram             |            |            |
|  |                    | DRUG SUPPI              | LY CHAIN SECURITY ACT (     | DSCSA) INFO     | RMATION         |                       |   |                           |                                      |                     |                                 | Milliliter       |            |            |
|  |                    |                         |                             | _               |                 |                       |   |                           |                                      |                     |                                 |                  |            |            |
| Does supplier meet DSCSA definit   | tion of manufactur | rer?                    | Yes                         | _               | GLN:            | 0331722000000         |   |                           | ITEN                                 | AND PACKING II      | NFORMATION                      | N                |            |            |
| Is product exempt from DSCSA?  |                    |                         | No                          |                 |                 |                       |   | _                         |                                      |                     |                                 |                  |            |            |
| If yes, select exemption:  |                    |                         |                             |                 | GCP:            |                       |   |                           | Weight Lbs.                          |                     | ons (US msm                     | •                | Volume     | Saleable # |
| Other exemption - Write in:  |                    |                         |                             |                 |                 |                       |   |                           | Weight Lbs.                          | Depth               | Width                           | Height           | (Cube)     | Pieces     |
| Is product repackaged?   |                    |                         | No                          |                 |                 | iginal product purch  | ased  | Item/Each:                | 0.55                                 | 2.87                | 2.87                            | 5                | 41.18      | 1          |
| Is product sold by manufacturer's  |                    |                         | Yes                         | _               | direct from m   |                       |   |                           |                                      | -                   | -                               |                  |            |            |
| Has FDA granted waiver/exception   |                    | roduct?                 | No                          |                 | Provide source  | ce manufacturer for r | epackaged product   | Box/Carton/B              | undle/                               |                     |                                 |                  |            |            |
| If yes, attach documentation fron  | n FDA.             |                         |                             |                 |                 |                       |   | Inner Pack:               |                                      |                     |                                 |                  |            |            |
|  |                    | CT                      | IN AND HIBCC PRODUCT I      | NEORMATION      |                 |                       |   | Case:                     | 7.1                                  | 12                  | 9.18                            | 5.75             | 633.42     | 12         |
|  |                    | GII                     | IN AND HIBCC PRODUCT I      | NFORWATION      |                 |                       |   | Pallet:                   |                                      |                     |                                 |                  |            |            |
| Saleable Unit of Measure   | 9                  | Saleable Quantity       | HIBCC                       |                 | GTII            | N-14                  | Unit of Use GTIN-14   | railet.                   |                                      |                     |                                 |                  |            |            |
| X Item/Each  |                    | 1                       | TIIDOO                      |                 |                 | 31722066051           | Offic of Ose Grin-14  |                           |                                      |                     |                                 |                  |            |            |
| Box/Carton/Bundle/Inner Pack   |                    |                         |                             |                 |                 |                       |   |                           | COST INFORMATION                     |                     |                                 | WHOL <u>ESAL</u> | ER USE ONL | _Y:        |
| X Case   |                    | 12                      |                             |                 | 3033            | 31722066052           |   |                           |                                      |                     |                                 |                  |            |            |
| Pallet   |                    |                         |                             |                 |                 |                       |   | Regular Cost              |                                      |                     | Vendor #:                       |                  |            |            |
|  |                    |                         |                             |                 |                 |                       |   | Invoice Cost (            | WAC) (\$)                            | \$100.00            | Whsl. Code                      | #:               |            |            |
|  |                    |                         |                             |                 |                 |                       |   |                           |                                      |                     | Fineline Cod                    | de:              |            |            |
|  |                    |                         |                             |                 |                 |                       |   | As of date:               | 10/16/2023                           |                     | ļ                               |                  |            |            |
|  | ]                  |                         |                             |                 |                 |                       |   |                           |                                      |                     |                                 |                  |            |            |
|  |                    |                         |                             |                 |                 |                       |   | 11                        |                                      |                     | 1                               |                  |            |            |
|  |                    |                         |                             |                 |                 |                       |   |                           |                                      |                     |                                 |                  |            |            |
| *Please provide any additional info  | _                  | _                       | Attach copy of SAFETY DA    | ATA SHEET (SI   | S) or non haza  |                       | ISERT, LABEL AND PHOTO OF<br>esignated Drop Ship Only.                  | PRODUCT PACKA             | GING and BARCODE. Signature:         |                     |                                 |                  |            |            |



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

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIA.   | L HAZARD CLASSIFICATION and TRANSPORTATION  |  |  |  |  |  |
|--|---|--|--|--|--|--|
| Is this product (check all that apply): a. Cytotoxic?  | 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?  Does the product label bear a CA Prop 65 warning?  | 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 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  |  |  |  |  |  |
|  | 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#: NCPDP#: NPI #: |  |  |  |  |  |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);   | Comments  |  |  |  |  |  |
| SP#  | Registry: No Registry Program Contact Name: Phone:  |  |  |  |  |  |
| ADD'L STORAGE INFORMATION  | Comments  |  |  |  |  |  |
| ARCOS Reportable? No If yes, indicate which:   | Contact tel. # if product received damaged:  1-866-827-3647  Is product returnable for credit:  Yes   |  |  |  |  |  |
|  | URL/Link to returns policy: contact - customerservice@camberpharma.com  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:   | Special regulations or returns requirements for this  |  |  |  |  |  |
| Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  | product in certain states?  If so, which states? Other requirements? Comments?  |  |  |  |  |  |
| Comments:  |   |  |  |  |  |  |
| MISCEL   | ANEOUS NOTES and/or Image of Product Barcode:   |  |  |  |  |  |
|  |   |  |  |  |  |  |



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#### 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?  |