



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

Version 2020

Introduction Type:  Open Stock

Final Version

Date:

## PRODUCT INFORMATION

Company Name:  Application:

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

DUNS:

Proprietary Name (if Applicable) and Established Name:

Selling Unit NDC:  Unit of Use NDC:  UPC:

UDI:  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:  Address 2:

City:  State:  Zip:

Key Contact:  Email:

Phone Number:  Fax:

Product Therapeutic Classification:

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:

Name:

Number:

Group E-mail:

c. Special regulations for product in any states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life:  Months

Initial shelf life at launch (if different):  Months

| ADDITIONAL PRODUCT INFORMATION   |  | PRODUCT DESCRIPTION INFORMATION   |  |
|--|--|---|--|
| The product is a legend device? <input type="text" value="No"/>                          | Is the Product... <input type="text" value="Direct-Ship Only"/>                                | Size: <input type="text" value="3 x 28 Pack"/>  |  |
| if yes, enter class # <input type="text"/>   | Is the Product... <input type="text" value="Neither"/>   | Strength: <input type="text" value="1mg/0.02mg"/>   |  |
| if yes, list NDCs of product kit? <input type="text"/>                                   | Orphan Drug Status <input type="text"/>  | Dosage Form: <input type="text" value="Chewable Tablets"/>                                  |  |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/>              | FDA Approval Status <input type="text"/>   | Product Shape: <input type="text" value="Round"/>   |  |
| co-licensed? <input type="text" value="No"/>   | Allergens Present <input type="text" value="Not made with natural rubber latex."/>             | Product Color: <input type="text" value="24 white active; 4 brown non-hormonal placebo"/>   |  |
| latex-free? <input type="text" value="No"/>  | Country of Origin <input type="text" value="Spain"/>   | Product Imprint: <input type="text" value="24 active imprinted XI and T4; 4 non-hormonal"/> |  |
| preservative-free? <input type="text" value="Yes"/>                                      | Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/> |   |  |
| correctional institution block? <input type="text" value="Yes"/>                         |  |   |  |
| 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"/>                                    |  |   |  |

## ORDER INFORMATION

Unit of Sale

|                                     |                   |
|-------------------------------------|-------------------|
| <input type="checkbox"/>            | Bottle            |
| <input checked="" 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 Power Multi  |
| <input type="checkbox"/>            | Other: Write In   |

What is the NDC selling unit?

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?

|                                 |                   |
|---------------------------------|-------------------|
| <input type="text" value="64"/> | Each              |
| <input type="text"/>            | Inner/Carton/Pack |
| <input type="text"/>            | Case              |

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:   Authorized Generic  If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

|                                     |            |
|-------------------------------------|------------|
| <input checked="" type="checkbox"/> | Each       |
| <input type="checkbox"/>            | Gram       |
| <input type="checkbox"/>            | Milliliter |

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

Is product exempt from DSCSA?

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?

GLN:

If Yes, was original product purchased direct from mfr?

If yes, attach documentation from FDA.

## ITEM AND PACKING INFORMATION

| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |         |        | Volume (Cube) | # Pieces: |
|-------------------------------|-------------|------------------------|---------|--------|---------------|-----------|
|                               |             | Depth                  | Width   | Height |               |           |
| Box/Carton/Bundle/Inner Pack: | 0.18        | 4.409                  | 2.362   | 2.756  | 28.701144     | 1         |
| Case:                         | 11.6        | 19.448                 | 11.5748 | 9.114  | 2051.6226     | 64        |
| Pallet:                       |             |                        |         |        | 0             |           |

## GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure                              | Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|---|----------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each         | 1        |       | 00370700101858 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |          |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 64       |       | 10370700101855 |                     |
| <input type="checkbox"/> Pallet                       |          |       |                |                     |

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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 2020

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? <span style="float: right;">No</span></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?<br/>           Is the product a CA Prop 65 carcinogen? <span style="float: right;">No</span><br/>           Is the product a CA Prop 65 reproductive toxicant? <span style="float: right;">No</span><br/>           Does the product label bear a CA Prop 65 warning? <span style="float: right;">No</span></p> <p>c. Contact Hazard? <span style="float: right;">No</span></p> <p>d. Does this product require special clean-up instructions?<br/>           (If yes, attach SDS with special instructions.) <span style="float: right;">No</span></p> <p>e. Does the product contain DEHP? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by DOT?<br/>           (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <input style="width: 100%;" type="text"/></p> <p>Is this product regulated for shipment by IATA?<br/>           (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <input style="width: 100%;" type="text"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger<br/> <input type="checkbox"/> Cargo<br/> <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <span style="float: right;">No</span><br/>           RQ Threshold: <input style="width: 100%;" type="text"/></p> <p>Is this a marine pollutant? <span style="float: right;">No</span></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br/>           No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity<br/> <input type="checkbox"/> Consumer Commodity, ORM-D<br/> <input type="checkbox"/> Small Quantity (49 CFR 173.4)<br/> <input type="checkbox"/> Special Permit; DOT-SP<br/> <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);<br/>           SP# <input style="width: 100%;" type="text"/></p> | <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">SDS Hazard Classification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td><input 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> <tr> <td colspan="2"><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td colspan="2">Is the product a NIOSH hazardous drug? <span style="float: right;">No</span></td> </tr> <tr> <td colspan="2">If yes, indicate which: <input style="width: 100%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td>EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/></td> <td>Waste Characteristics <input style="width: 40%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? <span style="float: right;">No</span></p> <p>If Yes, is it managed with a pharmacy registry?<br/>           Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <span style="float: right;">No</span></p> <p>Limited Distribution Requirement <span style="float: right;">No</span></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b></p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>REMS Program Manager Name: <input style="width: 60%;" type="text"/></td> <td>Phone: <input style="width: 40%;" type="text"/></td> </tr> <tr> <td>Supplier Manages REMS registry exclusively: <input style="width: 60%;" type="text"/></td> <td></td> </tr> <tr> <td>Wholesale distributor support: <input style="width: 60%;" type="text"/></td> <td></td> </tr> <tr> <td>Provider Name: <input style="width: 60%;" type="text"/></td> <td>DEA #: <input style="width: 40%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 60%;" type="text"/></td> <td>PCPDP#: <input style="width: 40%;" type="text"/></td> </tr> <tr> <td></td> <td>NPI #: <input style="width: 40%;" type="text"/></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>Registry Program Contact Name: <input style="width: 60%;" type="text"/></td> <td>Phone: <input style="width: 40%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table> | <input 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 type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/> |  | Is the product a NIOSH hazardous drug? <span style="float: right;">No</span> |  | If yes, indicate which: <input style="width: 100%;" type="text"/> |  | EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/> | Waste Characteristics <input style="width: 40%;" type="text"/> | REMS Program Manager Name: <input style="width: 60%;" type="text"/> | Phone: <input style="width: 40%;" type="text"/> | Supplier Manages REMS registry exclusively: <input style="width: 60%;" type="text"/> |  | Wholesale distributor support: <input style="width: 60%;" type="text"/> |  | Provider Name: <input style="width: 60%;" type="text"/> | DEA #: <input style="width: 40%;" type="text"/> | Site Enrollment Number assigned by Supplier: <input style="width: 60%;" type="text"/> | PCPDP#: <input style="width: 40%;" type="text"/> |  | NPI #: <input style="width: 40%;" type="text"/> | Registry Program Contact Name: <input style="width: 60%;" type="text"/> | Phone: <input style="width: 40%;" type="text"/> | Comments <input style="width: 100%;" type="text"/> |  |
| <input 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 type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| If yes, indicate which: <input style="width: 100%;" type="text"/>   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/>  | Waste Characteristics <input style="width: 40%;" type="text"/>  |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| REMS Program Manager Name: <input style="width: 60%;" type="text"/>   | Phone: <input style="width: 40%;" type="text"/>   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Supplier Manages REMS registry exclusively: <input style="width: 60%;" type="text"/>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Wholesale distributor support: <input style="width: 60%;" type="text"/>   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Provider Name: <input style="width: 60%;" type="text"/>   | DEA #: <input style="width: 40%;" type="text"/>   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Site Enrollment Number assigned by Supplier: <input style="width: 60%;" type="text"/>   | PCPDP#: <input style="width: 40%;" type="text"/>  |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
|   | NPI #: <input style="width: 40%;" type="text"/>   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Registry Program Contact Name: <input style="width: 60%;" type="text"/>   | Phone: <input style="width: 40%;" type="text"/>   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| Comments <input style="width: 100%;" type="text"/>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| ADD'L STORAGE INFORMATION   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| <p>Is the Product...</p> <p>Controlled Substance? <span style="float: right;">No</span>      Controlled Substance Code <input style="width: 100%;" type="text"/></p> <p>Controlled by State(s)? <span style="float: right;">No</span>      Listed Chemical (List I or II) <span style="float: right;">No</span></p> <p>ARCOS Reportable? <span style="float: right;">No</span>      If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input style="width: 100%;" type="text"/>      Is it a scheduled listed chemical product?: <input style="width: 100%;" type="text"/></p>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| CLASS OF TRADE RESTRICTION:   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">Yes</span></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| RETURN INSTRUCTIONS   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| <p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 100%;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| MISCELLANEOUS NOTES and/or Image of Product Barcode:  |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |
| <input style="width: 100%; height: 40px;" type="text"/>   |   |                                  |                                    |                                    |                                   |   |   |  |  |  |  |   |  |  |  |   |   |  |  |   |  |   |   |   |  |  |   |   |   |  |  |

