



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Product  Post Launch Change

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:  Individual Unit NDC:  UPC:

UDI:  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:

Address 2:

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):

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:  
 Initial shelf life at launch (if different):  Months

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product... Direct-Ship Only   
 Is the Product... Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose NDC, indicate NDC here:

Country of Origin:

Is this product covered under the Trade Agreements Act (TAA)?

**PRODUCT DESCRIPTION INFORMATION**

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

**ORDER INFORMATION**

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 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?  
 Each  
 Inner/Carton/Pack  
 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?

Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  GLN:

Is product exempt from DSCSA?

If yes, select exemption:  
 Other exemption - Write in:

Is product repackaged?  If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?  If yes, attach documentation from FDA.

**ITEM AND PACKING INFORMATION**

| Item:                         | Weight Lbs. | Dimensions (US msmts.) |        |       | Volume (Cube) | # Pieces: |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
|                               |             | Depth                  | Height | Width |               |           |
| Box/Carton/Bundle/Inner Pack: | 0.1         |                        | 3.25   | 1.5   |               |           |
| Case:                         | 1.35        | 6.625                  | 3.5    | 4.875 | 0.065         | 12        |
| Pallet:                       | 20.55       | 15.5                   | 9.25   | 13.75 | 1.141         | 96        |
| UPC:                          | Case:       |                        |        |       |               |           |
|                               | Carton:     |                        |        |       |               |           |

**GTIN PRODUCT INFORMATION**

| Serialized?       | Yes                              | Level  |                                     | Quantity | GTIN-14        |
|-------------------|----------------------------------|--|-------------------------------------|----------|----------------|
|                   |                                  | Item   | Saleable Unit                       |          |                |
| If not, when?     | <input type="text"/>             | <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | <input checked="" type="checkbox"/> | 1        | 00331722746908 |
| Items aggregated? | <input type="text" value="Yes"/> | <input checked="" type="checkbox"/> Case                         | <input checked="" type="checkbox"/> | 12       | 10331722746905 |
|                   |                                  | <input checked="" type="checkbox"/> Pallet                       | <input checked="" type="checkbox"/> | 96       | 30331722746909 |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |
|                   |                                  | <input type="checkbox"/>   | <input type="checkbox"/>            |          |                |

**COST INFORMATION**

Regular Cost

Invoice Cost (WAC) (\$)

Federal Excise Tax Per Unit of Sale

As of date:

**WHOLESALE USE ONLY:**

Vendor #:

Whsl. Code #:

Fineline Code:

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? No

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? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No

(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?

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. (inc. N for non-narcotic)

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 No

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

### SDS Hazard Classification

|  |   |
|--|---|
| <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? <input style="width: 100%;" type="text"/>                               |   |
| If yes, indicate which: <input style="width: 100%;" type="text"/>  |   |

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #: No

PCPDP #: No

NPI #: No

Comments:

**Registry:** No

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

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

**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  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
|--|--|---|--------|-------------------------------------|-----------|---|-----------|-------------------------------------|---|-------------------------------------|-----------|--|---------------------------|-----------|---|---|--|--|
| <p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 40%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><u>No</u></td> <td>Fax Number: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax Number: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><u>No</u></td> <td>Phone No.: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><u>No</u></td> <td>Site Address: <input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <u>case pack</u></p> <p>Supplier's Customer Service Number: <u>732-529-0430 x466 x465 x467 x470</u></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Name: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Phone: <input style="width: 100%;" type="text"/></td> </tr> </table> | a. EDI   | <u>Yes</u>  |        | b. Autofax                          | <u>No</u> | Fax Number: <input style="width: 100%;" type="text"/> | c. Fax    | <u>Yes</u>                          | Fax Number: <input style="width: 100%;" type="text"/> | d. Phone only                       | <u>No</u> | Phone No.: <input style="width: 100%;" type="text"/> | e. Supplier Web Site only | <u>No</u> | Site Address: <input style="width: 100%;" type="text"/> | Name: <input style="width: 100%;" type="text"/> | Phone: <input style="width: 100%;" type="text"/> | <p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text" value="2:30PM"/> Eastern</p> <hr/> <p>Shipping lead time of PO: <input style="width: 50px;" type="text" value="24/48"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text" value="No"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text" value="No"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text" value="Yes"/></p> |
| a. EDI   | <u>Yes</u>   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| b. Autofax   | <u>No</u>  | Fax Number: <input style="width: 100%;" type="text"/>   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| c. Fax   | <u>Yes</u>   | Fax Number: <input style="width: 100%;" type="text"/>   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| d. Phone only  | <u>No</u>  | Phone No.: <input style="width: 100%;" type="text"/>    |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| e. Supplier Web Site only  | <u>No</u>  | Site Address: <input style="width: 100%;" type="text"/> |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Name: <input style="width: 100%;" type="text"/>  |  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Phone: <input style="width: 100%;" type="text"/>   |  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Expedited Freight Charges or Other Designated Drop Ship Fees:  | Overnight and Priority Overnight PO Processing   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <p>Expedited freight fees billed with each order: <input style="width: 50px;" type="text" value="No"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text" value="No"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text" value="No"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>   | <p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text" value="Yes"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text" value="2:30PM"/> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 20px; text-align: center;"><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text" value="Yes"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text" value="2:30PM EST"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text" value="No"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text" value="No"/> Phone #: <input style="width: 100px;" type="text"/></p> <p>Fax: <input style="width: 50px;" type="text" value="Yes"/> Fax #: <input style="width: 100px;" type="text" value="732-562-8788"/></p> <p>EDI: <input style="width: 50px;" type="text" value="Yes"/></p> <p>Overnight Fees apply: <input style="width: 50px;" type="text" value="Yes"/></p> <p>Other fees apply: <input style="width: 50px;" type="text" value="No"/></p> | <input checked="" type="checkbox"/>                     | Monday | <input checked="" type="checkbox"/> | Tuesday   | <input checked="" type="checkbox"/>                   | Wednesday | <input checked="" type="checkbox"/> | Thursday  | <input checked="" type="checkbox"/> | Friday    |  |                           |           |   |   |  |  |
| <input checked="" type="checkbox"/>  | Monday   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <input checked="" type="checkbox"/>  | Tuesday  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <input checked="" type="checkbox"/>  | Wednesday  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <input checked="" type="checkbox"/>  | Thursday   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <input checked="" type="checkbox"/>  | Friday   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Class of Trade Restriction:  | Return Instructions  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text" value="No"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text" value="Yes"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text" value="No"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text" value="No"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>   | <p>Contact # if product is received damaged: <input style="width: 150px;" type="text" value="732-529-0430"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text" value="Yes"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text" value="Yes"/></p> <p>If so, which states? Other requirements? Comments?<br/><input style="width: 100%; height: 40px;" type="text"/></p>   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Other Data Information Required to Process PO:   | ADDITIONAL INFORMATION   |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 150px;" type="text"/></p> <p>Physician State License #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 150px;" type="text"/></p>   | <p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text" value="No"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text" value="No"/></p>  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| Miscellaneous Notes:   |  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |
| <input style="width: 100%; height: 60px;" type="text"/>  |  |   |        |                                     |           |   |           |                                     |   |                                     |           |  |                           |           |   |   |  |  |