



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

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:

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):

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

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

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?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?

If Yes, was original product purchased direct from mfr?

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: | 0.3 | 2.3 | 4.8 | 2.3 | 25.392 | 1 |
| Case: | 7.2 | 14.4 | 5.3 | 9.7 | 740.304 | 24 |
| Pallet: | 777.6 | 48 | 55.5 | 40 | 106,560 | 108 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

GTIN PRODUCT INFORMATION

| Serialized? | If not, when? | Items aggregated? | Level | | Unit | Quantity | GTIN-14 |
|-------------------------------------|--------------------------------------|----------------------------------|-------------------------------------|--------------------------|------|----------|----------------|
| | | | Item | Saleable | | | |
| <input checked="" type="checkbox"/> | <input type="text" value="Q4 2017"/> | <input type="text" value="Yes"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 2D | 1 | 00324979011127 |
| <input checked="" type="checkbox"/> | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 2D | 12 | 30324979011128 |
| <input checked="" type="checkbox"/> | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 2D | 24 | 60324979011129 |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | 2D | | |

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?

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? No

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit? No
(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (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: No

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

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

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:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product 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 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: 20%;">a. EDI</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table> | a. EDI | <input type="text"/> | | | | b. Autofax | <input type="text"/> | Fax Number: | <input type="text"/> | | c. Fax | <input type="text"/> | Fax Number: | <input type="text"/> | | d. Phone only | <input type="text"/> | Phone No.: | <input type="text"/> | | e. Supplier Web Site only | <input type="text"/> | Site Address: | <input type="text"/> | | Name: | <input type="text"/> | Phone: | <input type="text"/> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p> |
| a. EDI | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| b. Autofax | <input type="text"/> | Fax Number: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| c. Fax | <input type="text"/> | Fax Number: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| d. Phone only | <input type="text"/> | Phone No.: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| e. Supplier Web Site only | <input type="text"/> | Site Address: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input 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 type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p> | <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 20%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p> | <input type="checkbox"/> | Monday | <input type="checkbox"/> | Tuesday | <input type="checkbox"/> | Wednesday | <input type="checkbox"/> | Thursday | <input type="checkbox"/> | Friday | Phone: | <input type="text"/> | Phone #: | <input type="text"/> | Fax: | <input type="text"/> | Fax #: | <input type="text"/> | EDI: | <input type="text"/> | | | | | | | | | |
| <input type="checkbox"/> | Monday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Tuesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Wednesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Thursday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Friday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input type="text"/> | Phone #: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax: | <input type="text"/> | Fax #: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| EDI: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Class of Trade Restriction: | Return Instructions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Miscellaneous Notes: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input style="width: 100%; height: 80px;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |