



Standard Pharmaceutical Product Information (Rx Product Only)

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:
 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
 yes Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power 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 | | |
| Item: | 0.11 | NA | 3 | 1.73 | #VALUE! | 60 Tablets per Bottle |
| Box/Carton/Bundle/Inner Pack: | NA | NA | NA | NA | #VALUE! | NA |
| Case: | 4 | 12.2 | 4.5 | 8.4 | 461.16 | 24 Bottles per Case |
| Pallet: | 680 | 48 | 48 | 40 | 92160 | 160 Cases per Bottle |
| UPC: | Case: | 350228381604 | | | | |
| | Carton: | | | | | |

GTIN PRODUCT INFORMATION

| Serialized? If not, when? Items aggregated? | Yes <input type="text"/> | Level | Saleable Unit | Quantity | GTIN-14 |
|---------------------------------------------------|-------------------------------------|------------------------------|-------------------------------------|----------|----------------|
| | | | | | |
| | <input checked="" type="checkbox"/> | Item | <input checked="" type="checkbox"/> | 1 | 00350228381604 |
| | <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | | | |
| | <input checked="" type="checkbox"/> | Case | <input checked="" type="checkbox"/> | 24 | 20350228381608 |
| | | Pallet | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 Federal Excise Tax Per Unit of Sale
 As of date:

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Finline 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:

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?
(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?
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?
Schedule No. (inc. N for non-narcotic)
Controlled Substance Code
Listed Chemical (List I or II)
If yes, indicate which:
Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

SDS Hazard Classification
[X] Organic
Inorganic
Steroid/Androgen
Corrosive
Oxidizer
Contact Hazard
Aerosol Class; Identify NFPA Storage Level:
Is the product a NIOSH hazardous drug? No
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:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:
DEA #:
PCPDP #:
NPI #:

Registry:
Registry Program Contact Name:
Phone:
Comments:

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: 1877-671-6307
Is product returnable for credit:
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 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: Name: _____ Phone: _____ | Purchase order daily receipt cut off time by supplier Cut off time: _____ Shipping lead time of PO: _____ Hours _____ Days Ships same day for next day receipt: <input type="checkbox"/> _____ Ships for second day receipt: <input type="checkbox"/> _____ Ships regular ground for 3-10 days receipt: <input type="checkbox"/> _____ |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: <div style="border: 1px solid gray; height: 80px; width: 100%;"></div> | Overnight receipt available: <input type="checkbox"/> _____ PO Receipt cut off time: _____ Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Saturday Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: <input type="checkbox"/> _____ Other fees apply: <input type="checkbox"/> _____ |
| Class of Trade Restriction: | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> _____ Restricted to retail pharmacy only: <input type="checkbox"/> _____ Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> _____ Restricted from US territories? (explain in comments) <input type="checkbox"/> _____ Comments: <div style="border: 1px solid gray; height: 60px; width: 100%;"></div> | |
| Other Data Information Required to Process 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: <input type="checkbox"/> _____ URL/Link to returns policy: _____ Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? <div style="border: 1px solid gray; height: 40px; width: 100%;"></div> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <div style="border: 1px solid gray; height: 80px; width: 100%;"></div> | Is product order for scheduled patient procedure? <input type="checkbox"/> _____ Is product order for restocking purposes? <input type="checkbox"/> _____ |