



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Drug Post Launch Change

Final Version

Date: 1/24/2020

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
 Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 co-licensed?
 Is the Product...
 Is the Product...
 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		
Item:	0.18	2	4	2	16	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	5.21	12.5	5.25	8.75	574.22	24
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Saleable Unit	Quantity	GTIN-14
<input type="text" value="Yes"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text" value="1"/>	<input type="text" value="00359746339906"/>
	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text" value="24"/>	<input type="text" value="40359746339904"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION

Regular Cost:
 Invoice Cost (WAC) (\$):
 Federal Excise Tax Per Unit of Sale:
 As of date:
 Vendor #:
 Whsl. Code #:
 Finesse 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?

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)

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 Yes

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	
<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: <input style="width: 100%;" type="text"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input style="width: 100%;" type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? No	
If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/>	
Website URL: <input style="width: 100%;" type="text"/>	
Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/>	
REMS: No	
REMS Program Manager Name: <input style="width: 100%;" type="text"/>	Phone: <input style="width: 100%;" type="text"/>
Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/>	
Wholesale distributor support: <input style="width: 100%;" type="text"/>	
Provider Name: <input style="width: 100%;" type="text"/>	
Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/>	DEA #: <input style="width: 100%;" type="text"/>
	PCPDP #: <input style="width: 100%;" type="text"/>
	NPI #: <input style="width: 100%;" type="text"/>

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: 50%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 20%;"></td> <td style="width: 15%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Phone No.:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Site Address:</td> <td><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 50px;" type="text" value="24"/></p> <p>Supplier's Customer Service Number: <input style="width: 100%;" type="text" value="(410) 912-3722"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes			b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>	c. Fax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>	d. Phone only	<input type="checkbox"/>		Phone No.:	<input style="width: 100%;" type="text"/>	e. Supplier Web Site only	<input type="checkbox"/>		Site Address:	<input style="width: 100%;" type="text"/>	Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 100%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
a. EDI	<input type="checkbox"/>	Yes																												
b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>																										
c. Fax	<input type="checkbox"/>	Yes	Fax Number:	<input style="width: 100%;" type="text"/>																										
d. Phone only	<input type="checkbox"/>		Phone No.:	<input style="width: 100%;" type="text"/>																										
e. Supplier Web Site only	<input type="checkbox"/>		Site Address:	<input style="width: 100%;" type="text"/>																										
Name:	<input style="width: 80%;" type="text"/>																													
Phone:	<input style="width: 80%;" 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"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 100%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%;"> <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 style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100%;" type="text"/></p> <p>Saturday Overnight receipt available: <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 30%;"><input style="width: 100%;" type="text"/></td> <td style="width: 10%;">Phone #:</td> <td style="width: 40%;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 100%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 100%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" 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 style="width: 100%;" type="text"/>	Phone #:	<input style="width: 100%;" type="text"/>	Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>	EDI:	<input style="width: 100%;" type="text"/>									
<input type="checkbox"/>	Monday																													
<input type="checkbox"/>	Tuesday																													
<input type="checkbox"/>	Wednesday																													
<input type="checkbox"/>	Thursday																													
<input type="checkbox"/>	Friday																													
Phone:	<input style="width: 100%;" type="text"/>	Phone #:	<input style="width: 100%;" type="text"/>																											
Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>																											
EDI:	<input style="width: 100%;" type="text"/>																													
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"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" 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: 50px;" 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 style="width: 100%;" type="text"/></p> <p>Physician Name: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100%;" type="text"/></p> <p>Physician State License #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																													
Miscellaneous Notes:																														
<input style="width: 100%; height: 100px;" type="text"/>																														