



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

Version 2020

Introduction Type: New Item

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

ADDITIONAL PRODUCT INFORMATION

The product is?
 a legend device?
 if yes, enter class #
 a product kit?
 if yes, list NDCs of component parts
 reverse numbered?
 co-licensed?
 latex-free?
 preservative-free?
 correctional institution block?
 opioid?
 Cannabinoid?
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose, indicate NDC here:

Is the Product... Direct And Drop-Ship
 Is the Product... Neither
 Orphan Drug Status

FDA Approval Status

Allergens Present

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

Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

ITEM AND PACKING INFORMATION

Item/Each:	Gross Weight		Dimensions (US msmts.)			Volume (Cube)	# Pieces:
	Lbs.		Depth	Width	Height		
Item/Each:	0.71		4.69	3.03	3.03	43.06	1
Box/ Carton/ Bundle/ Inner Pack:	5.56		9.61	6.54	6.07	381.50	6
Case:	22.25		14.02	10.55	12.99	1921.31	24
Pallet:	667.51		47.24	39.38	45.28	84242.02	792

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		00372241010118	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	6		20372241010112	
<input checked="" type="checkbox"/> Case	24		40372241010116	
<input checked="" type="checkbox"/> Pallet	792		50372241010113	

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:

Wholesaler Use Only:
 Vendor #:
 Whsl. Code #:
 Fineline Code:

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

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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? No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Yes Is the product a CA Prop 65 reproductive toxicant? Yes Does the product label bear a CA Prop 65 warning? No</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) Yes</p> <p>a. UN/Identification Number <input type="text" value="UN3077"/></p> <p>b. Proper Shipping Name <input type="text" value="Environmentally hazardous substances, solid, n.o.s."/></p> <p>c. DOT Hazard Class <input type="text" value="9"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? No</p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input checked="" type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? Yes</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <p><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</p> <p><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/></p>
<p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">Hazardous Waste Identification</div> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p>
<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">ADD'L STORAGE INFORMATION</div> <p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) No</p> <p>ARCOS Reportable? No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: No</p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? <input type="text"/> Website URL: <input type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> PCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>
<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes</p> <p>Restricted to retail pharmacy only: No</p> <p>Restricted to hospital, clinics, and physician offices only: No</p> <p>Restricted from US territories? (explain in comments) No</p> <p>Comments: <input type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div>	



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

Version 2021

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> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
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 type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>