



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

Version 2020

Introduction Type: New Product Post Launch Change

Final Version

Date: 8/8/2022

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:
 Phone Contact: Email:
 Key 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		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
latex-free?	<input type="text" value="Yes"/>	Allergens Present	<input type="text"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="Italy"/>
correctional institution block?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	<input type="text" value="500 count"/>
		Strength:	<input type="text" value="10 mg"/>
		Dosage Form:	<input type="text" value="Tablets"/>
		Product Shape:	<input type="text" value="Capsule Shape"/>
		Product Color:	<input type="text" value="White to Off-White"/>
		Product Imprint:	<input type="text" value="*ZF 40*"/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 500 tablets"/> (Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Box/Carton	
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? <input type="text" value="Yes"/>
	If Yes, how many of which package type?
	<input type="text" value="12"/> Each
	<input type="text" value="1"/> Inner/Cartron/Pack
	<input type="text" value="1"/> 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? If Yes, was original product purchased direct from mfr?
 Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.31	2.12	2.12	3.97		1
Box/Cartron/Bundle/Inner Pack:						
Case:	5.78	6.65	8.86	4.88		12
Pallet:	1029.99	47.24	39.37	49.21		2,100

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		00372578004057	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40372578004055	
<input checked="" type="checkbox"/> Pallet	2,100		50372578004052	

COST INFORMATION

Regular Cost:
 Invoice Cost (WAC) (\$):
 As of date:
 Vendor #:
 Whsl. Code #:
 Finesline Code:

Version 2020

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? No Is the product a CA Prop 65 reproductive toxicant? No 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) 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? <input type="text"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? No</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="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;"><input type="checkbox"/> Organic</td> <td style="border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/> </td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/> </td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">Hazardous Waste Identification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;">EPA Hazardous Waste Code: <input type="text"/></td> <td style="border: none;">Waste Characteristics <input type="text"/></td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: 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:</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> </div>	<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 type="text"/>		Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/>		EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>
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ADD'L STORAGE INFORMATION													
<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) <input type="text"/></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?: <input type="text"/></p>													
CLASS OF TRADE RESTRICTION:													
<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 type="text"/></p>													
RETURN INSTRUCTIONS													
<p>Contact tel. # if product received damaged: <input type="text" value="888-304-5022"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input type="text" value="www.vionausa.com"/></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 type="text"/></p>													
MISCELLANEOUS NOTES and/or Image of Product Barcode:													
<input type="text"/>													

