



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

Version 2021

Introduction Type: New Item

Final Version

Date: 17.06.2024

PRODUCT INFORMATION

Company Name: Application:
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):
 Medical Device Class, if applicable:
 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?

e. Shelf life:
 Protect product (unit of sale) from light?
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION 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?	<input type="text" value="No"/> <input type="text"/> <input type="text"/> <input type="text" value="No"/> <input type="text" value="No"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Is the Product... Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Country of Origin Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Direct-Ship Only"/> <input type="text" value="Neither"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text" value="India"/> <input type="text" value="No"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="text"/> <input type="text"/>		
Size: <input type="text" value="60's"/>		Strength: <input type="text" value="30 mg"/>	
Dosage Form: <input type="text" value="Tablets"/>		Product Shape: <input type="text" value="Rectangular"/>	
Product Color: <input type="text" value="white to off white"/>		Product Imprint: <input type="text" value="Uncoated tablet with bisected score lines on one side and trisected"/>	

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 NO 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?
 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, attach documentation from FDA.
 GLN:
 GCP:
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.125	1.574	1.574	3.622	8.97	1
Box/Carton/Bundle/ Inner Pack:	1.673	6.811	5.118	3.937	137.24	12
Case:	8.614	12.598	9.055	11.024	1257.56	48
Pallet:	431.754	48	40	38.307	73549.44	2160

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00342543744035"/>	<input type="text"/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="12"/>	<input type="text"/>	<input type="text" value="20342543744039"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="48"/>	<input type="text"/>	<input type="text" value="50342543744030"/>	<input type="text"/>
<input checked="" type="checkbox"/> Pallet	<input type="text" value="2,160"/>	<input type="text"/>	<input type="text" value="70342543744034"/>	<input type="text"/>

COST INFORMATION

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

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