



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

Version 2021

Introduction Type:

Final Version

Date:

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:

Phone Number: Email:

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...

Is the Product...

Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)?

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:

II. Generic Equivalent to What Brand?:

Authorized Generic *If Authorized Generic, other section fields are not applicable

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:	0.0835	1.81	1.65	3.34	9.97491	1 Vial
Box/Carton/Bundle/Inner Pack:	1.243	11.6	3.77	4.33	189.35956	12 Vials
Case:	6.131	12.598	8.464	9.842	1049.4473	48 Vials
Pallet:	Air-425.424 Sea-523.520	48	40	Air-54.21 Sea-44.37	104083.2 Sea-	All-3040 Vials Sea-3072

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	1		00355150391011	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	12		30355150391012	
<input checked="" type="checkbox"/> Case	48		50355150391016	
<input checked="" type="checkbox"/> Pallet	3840		70355150391010	

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:
 Vendor #:

Whsl. Code #:

Fineline Code:



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PRODUCT INFORMATION	
Company Name:	Eugia US LLC
Application:	ANDA
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:	55150-392-01
Unit of Use NDC:	55150-392-01
UPC:	355150392018
UDI	
CVX Code:	
MVX Code:	
Description:	Bendamustine Hydrochloride for Injection, USP 100 mg per Vial
Active Ingredient(s):	
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Address 2:	
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	
Notes	<input type="text" value="Discard unused portion"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
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?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value=""/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
The product is?	Size:
a legend device?	<input type="text" value="1 Single-Dose Vial"/>
if yes, enter class #	Strength:
a product kit?	<input type="text" value="100 mg per Vial"/>
if yes, list NDCs of component parts	Dosage Form:
reverse numbered?	<input type="text" value="Solution"/>
co-licensed?	Product Shape:
latex-free?	<input type="text" value="Vial Pack"/>
preservative-free?	Product Color:
correctional institution block?	Product Imprint:
opioid?	
Cannabinoid?	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	
Is the Product... Orphan Drug Status?	
FDA Approval Status	
Allergens Present	
Country of Origin	<input type="text" value="India"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 1 Vial (55150-392-01)"/>
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity?
<input type="checkbox"/> Glass	<input type="text" value=""/>
<input type="checkbox"/> Tube	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Sgl	<input checked="" type="checkbox"/> Each
<input type="checkbox"/> Vial Liquid Multi	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Case
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value=""/> Authorized Generic
II. Generic Equivalent to What Brand?:	<input type="text" value=""/>
*If Authorized Generic, other section fields are not applicable	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 Vial"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	
If yes, attach documentation from FDA.	
GLN:	<input type="text" value=""/>
GCP:	<input type="text" value=""/>
If yes, was original product purchased direct from mfr?	<input type="text" value=""/>
Provide source manufacturer for repackaged product	<input type="text" value=""/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.178	2.16	2.16	4.33	20.202048	1 Vial
Box/ Carton/ Bundle/ Inner Pack:	2.551	9.48	7.32	5.31	368.48002	12 Vials
Case:	11.931	15.551	10.433	11.811	1916.259	48 Vials
Pallet:	Air-390.973 Sea-510.284	48	40	Air-52.24 Sea-40.43	100300.8 Sea-	All-1920 Vials Sea-1440

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	1		00355150392018	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	12		30355150392019	
<input checked="" type="checkbox"/> Case	48		50355150392013	
<input checked="" type="checkbox"/> Pallet	1920		70355150392017	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
As of date:		Fineline 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:

Chamala Narender