



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	<input type="text" value="Zyus Pharmaceuticals USA Inc."/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="78-905"/>		
Rx Product/Proprietary Name:	<input type="text" value="Glipizide and Metformin HCl Tablets, USP 2.5mg/500mg 100 count"/>		
NDC:	<input type="text" value="68382-185-01"/>	UPC:	<input type="text" value="368382185013"/>
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
Description:	<input type="text" value="white-colored, biconvex, modified capsule-shaped, film-coated tablet, debossed with 'ZE67' on one side and plain on other side"/>		
Active ingredients:	<input type="text" value="Glipizide &amp; Metformin"/>		
URL for Additional Product Information:	<input type="text" value="www.zyususa.com"/>		
Address:	<input type="text" value="73 Route 31 North"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="Pennington"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text"/>	Zip:	<input type="text" value="08534"/>
Phone Number:	<input type="text" value="(609) 730 1900"/>	Email:	<input type="text"/>
		Fax:	<input type="text" value="(609) 730 1991"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text"/>
Number:	<input type="text"/>
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>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	Initial shelf life at launch (if different): <input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Brand Name:	<input type="text" value="Metaglip"/>
III. Generic Equivalent for Brand:	<input type="text" value="Glipizide and Metformin HCl Tablets, USP 2.5mg/500mg 100 count"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/> Yes <input type="text" value="156861945"/> DUNS:
Is product exempt from DSCSA?	<input type="text" value="No"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/> No
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No
	If yes, attach documentation from FDA <input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	<input type="text" value="No"/> No
State Control?	<input type="text" value="No"/> No
ARCOS reportable?	<input type="text" value="No"/> No
Co-Licensed?	<input type="text" value="No"/> No
Controlled Substance?	<input type="text" value="No"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	89.9g		3.97	2.21	8.7737	
Box/ Carton:					0	
Case:	6.87 lbs	8.86	5.19	13.27	610.199718	24
Pallet:	643 lbs	47	39	47	86151	91
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text" value="1"/> (Write-in, e.g. 1 Vial)	<input type="text" value="100/2.5-500mg/Tablet"/>
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	<input type="text" value="Capsule"/>
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	<input type="text" value="White"/>
	Product Imprint:
	<input type="text" value="'ZE67'"/>

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$74.17	
As of date: <input type="text" value="8/2/2016"/>		

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: