



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc. Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	206748
Rx Product/Proprietary Name:	Glyburide and Metformin HCL Tablets, USP 5mg/500mg 100 count
NDC:	68382-655-01 UPC: 368382655011
CVX Code:	MXV Code:
Description:	pale yellow colored, capsule shaped, biconvex coated tablets, debossed with "655" on one side and plain on the other side
Active ingredients:	Glyburide & Metformin
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North Address 2:
City:	Pennington State: NJ Zip: 08534
Key Contact:	Email:
Phone Number:	(609) 730 1900 Fax: (609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<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="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	_____
Number:	_____
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<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:	AB II. Brand Name: Glucovance
III. Generic Equivalent for Brand:	Glyburide and Metformin HCL Tablets, USP 5mg/500mg 100 count

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

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

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	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? 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"/> Case
<input type="text"/> 1	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	17.5 g		3.97	2.21	8.7737	
Box/ Carton:					0	
Case:	7.76 lbs	8.86	5.1	13.28	600.07008	24
Pallet:	725 lbs	47	39	47	86151	91
UPC:	Case:					
	Carton:					

WHOLEALER USE ONLY:	
Vendor #:	_____
Whsl. Code #:	_____
Fineline Code:	_____

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
_____	100/5-500mg/Tablet
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsule
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	pale yellow
<input type="checkbox"/> Milliliter	Product Imprint:
	"655"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$8.95	
As of date: <input type="text" value="6/13/2016"/>		

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: _____



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Application Number for NDA/ANDA/BLA, Med Device:	206748
Rx Product/Proprietary Name:	Glyburide and Metformin HCL Tablets, USP 5mg/500mg 500 count
NDC:	68382-655-05 UPC: 368382655059
CVX Code:	MXV Code:
Description:	pale yellow colored, capsule shaped, biconvex coated tablets, debossed with "655" on one side and plain on the other side
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City:	Pennington State: NJ Zip: 08534
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III. Generic Equivalent for Brand:	Glyburide and Metformin HCL Tablets, USP 5mg/500mg 500 count

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If yes, select exemption:	_____
Other exemption - Write in:	_____
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(incl. N for non-narcotic)	
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Hazardous Material/Cytotoxic Agent?	No
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Is it reverse numbered?	_____

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<input type="checkbox"/> Tube	Minimum order quantity? Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
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<input type="checkbox"/> Other: Write In	<input type="text"/> Case
<input type="text"/> 1	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	74g		5.11	3.21	16.4031	
Box/ Carton:					0	
Case:	12.82 lbs	9.65	7.47	12.88	928.46124	12
Pallet:	987 lbs	47	39	47	86151	65
UPC:	Case:					
	Carton:					

WHOLEALER USE ONLY:	
Vendor #:	_____
Whsl. Code #:	_____
Fineline Code:	_____

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
_____ (Write-in, e.g. 1 Vial)	500/5-500mg/Tablet
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsule
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	pale yellow
	Product Imprint:
	"655"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$43.85	
As of date: <input type="text" value="6/13/2016"/>		

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

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