



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 Number for NDA/ANDA/BLA, Med Device:	206749
Rx Product/Proprietary Name:	Glyburide Tablets, USP 2.5mg 100 count
NDC:	68382-657-01
CVX Code:	
UPC:	368382657015
MVX Code:	
Description:	light yellow to yellow colored, may be spotted, round shaped, biconvex, uncoated tablets, debossed with "657" on one side and breakline on the other side
Active ingredients:	Glyburide
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Email:	
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:	Glyburide
III. Generic Equivalent for Brand:	Glyburide Tablets, USP 2.5mg 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	No
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:	43.15g		2.982	1.609	4.798038	
Box/ Carton:					0	
Case:	3.36 lbs	6.7	4.45	9.85	293.67775	24
Pallet:	684 lbs	47	39	47	86151	198
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text"/> (Write-in, e.g. 1 Vial)	100/2.5mg/Tablet
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Round
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	Light Yellow to Yellow
	Product Imprint:
	"657"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$16.00	
As of date: <input type="text" value="6/13/2016"/>		

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



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PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc. Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	206749
Rx Product/Proprietary Name:	Glyburide Tablets, USP 2.5 mg 500 count
NDC:	68382-657-05 UPC: 368382657053
CVX Code:	MXV Code:
Description:	light yellow to yellow colored, may be spotted, round shaped, biconvex, uncoated tablets, debossed with "657" on one side and breakline on the other side
Active ingredients:	Glyburide
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: Glyburide
III. Generic Equivalent for Brand:	Glyburide Tablets, USP 2.5 mg 500 count

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/>
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		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>	Unit of Sale	What is the NDC selling unit?
Legend Device?	No	<input checked="" type="checkbox"/> Bottle	Each
State Control?	No	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	Minimum order quantity? Yes <input type="checkbox"/>
Co-Licensed?	No	<input type="checkbox"/> Glass	If Yes, how many of which package type?
Controlled Substance?	No	<input type="checkbox"/> Tube	<input type="text"/> Each
Schedule No.?	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	<input type="text"/> Inner/ Carton/Pack
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	<input type="text"/> Case
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Powder Sgl	
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	
Is Item... _____		<input type="checkbox"/> Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
Is it reverse numbered?	<input type="checkbox"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	102.5 g		3.375	1.878	6.33825	
Box/ Carton:					0	
Case:	3.63 lbs	5.94	4.21	7.91	197.808534	12
Pallet:	774 lbs	47	39	47	86151	208
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text" value="500/2.5mg/Tablet"/>
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	Round
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	Light Yellow to Yellow
			<input type="checkbox"/> Gram	Product Imprint:	"657"
			<input type="checkbox"/> Milliliter		

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$78.00	
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: _____