



# 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:	206749
Rx Product/Proprietary Name:	Glyburide Tablets, USP 5 mg 100 count
NDC:	68382-658-01 UPC: 368382658012
CVX Code:	MVX Code:
Description:	light green colored, may be spotted, round shaped, biconvex, uncoated tablets, debossed with "658" 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*	
<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="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
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
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	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:	AB II. Brand Name: Glyburide
III. Generic Equivalent for Brand:	Glyburide Tablets, USP 5 mg 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
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:					

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

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
_____	100/5mg/ Tablet
(Write-in, e.g. 1 Vial)	Product Shape: Round
Rx billing unit to pharmacy:	Product Color: Light Green
<input checked="" type="checkbox"/> Each	Product Imprint: "658"
<input type="checkbox"/> Gram	
<input type="checkbox"/> Milliliter	

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$26.00	
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: \_\_\_\_\_



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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 5 mg 1000 count
NDC:	68382-658-10 UPC: 368382658104
CVX Code:	MXV Code:
Description:	light green colored, may be spotted, round shaped, biconvex, uncoated tablets, debossed with "658" 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

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<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)
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<b>b. Contact for temperature excursion questions:</b>	
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
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Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b> Yes	
Protect product (unit of sale) from light?	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:	AB II. Brand Name: Glyburide
III. Generic Equivalent for Brand:	Glyburide Tablets, USP 5 mg 1000 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		ORDER INFORMATION	
Is the Product... Direct Ship Item	No	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
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="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="checkbox"/> Vial Powder Sgl	
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	
Other: Write In	_____	<input type="checkbox"/> Other: Write In	
Is Item... _____			
If Unit Dose, is item bar coded to unit dose for hospital scanning?	_____		
Is it reverse numbered?	_____		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	166.85g		4.25	2.4	10.2	
Box/ Carton:					0	
Case:	5.6 lbs	7.36	5.23	9.8	377.22944	12
Pallet:	690 lbs	47	39	47	86151	120
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?	(Write-in, e.g. 1 Vial)	Size/Strength/Form:	1000/5mg/Tablet
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Shape:	Round
	<input type="checkbox"/> Gram	Product Color:	Light Green
	<input type="checkbox"/> Milliliter	Product Imprint:	"658"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$241.27	
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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