



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77-064
Rx Product/Proprietary Name:	Metformin HCl Tablets, 500 mg, 100 ct
NDC:	68382-028-01
UPC:	368382028013
CVX Code:	
MVX Code:	
Description:	White to off-white, round shaped, film-coated tablets debossed with the logo of 'Z' on one side and '70' on the other side.
Active ingredients:	Metformin HCl
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="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:	AB
II. Brand Name:	Glucophage
III. Generic Equivalent for Brand:	Metformin HCl Tablets, 500 mg, 100 ct

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

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
Legend Device?	<input type="text" value="No"/>	What is the NDC selling unit?	Each
State Control?	<input type="text" value="No"/>	(Write-in, e.g. 1 Box of 10 Vials)	
ARCOS reportable?	<input type="text" value="No"/>	Minimum order quantity?	<input type="text" value="Yes"/>
Co-Licensed?	<input type="text" value="No"/>	If Yes, how many of which package type?	
Controlled Substance?	<input type="text" value="No"/>	<input type="text"/>	Each
Schedule No.?	<input type="text"/>	<input type="text"/>	Inner/ Carton/Pack
(incl. N for non-narcotic)		<input type="text" value="1"/>	Case
Controlled Substance Code:	<input type="text"/>		
Hazardous Material/Cytotoxic Agent?	<input type="text" value="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"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	78.4 G		3.425	1.878	6.43215	
Box/ Carton:					0	
Case:	6.04LBS	7.52	4.33	11.3	367.94608	24
Pallet:		47.24	47.24	39.37	87858.7849	128
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:	100ct/500mg/Tablets
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:	White to off white
		<input type="checkbox"/> Gram		Product Imprint:	Z 70
		<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$8.26	
As of date: <input type="text" value="9/10/2014"/>		

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen  
 Reproductive Toxicant  
 Both  
 Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No  
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 (if yes, identify method below)

Limited Quantity  
 Consumer Commodity, ORM-D  
 Small Quantity (49 CFR 173.4)  
 Special Permit; DOT-SP  
 Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger  
 Cargo  
 Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization							
Serialized?	Yes	Level	How?	RFID	GTIN-14		
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	RFID	1036838208010
If not, when?	<input type="text"/>	Box/Carton	2D	Linear	<input type="checkbox"/>	RFID	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	RFID	
		Pallet	2D	Linear	<input type="checkbox"/>	RFID	

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<u>No</u>
If Yes, is it managed with a pharmacy registry?	<input type="text"/>
Website URL:	<input type="text"/>
Comments / Details: (For example, iPledge program?)	
<input type="text"/>	

### ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic  Inorganic  
 Antineoplastic  Steroid/Androgen  
 Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	877-993-8779
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	www.zydususa.com
Special regulations or returns requirements for this product in certain states?	<u>No</u>
If so, which states? Other requirements? Comments?	<input type="text"/>

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine  
 Pseudoephedrine  
 Phenylpropanolamine  
 Iodine (≥2.2%)  
 Other:

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:





# Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

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Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77-064
Rx Product/Proprietary Name:	Metformin HCl Tablets, 500 mg, 500 ct
NDC:	68382-028-05
CVX Code:	
UPC:	368382028051
MVX Code:	
Description:	White to off-white, round shaped, film-coated tablets debossed with the logo of 'Z' on one side and '70' on the other side.
Active ingredients:	Metformin HCl
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
Address 2:	
Email:	
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="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:	AB
II. Brand Name:	Glucophage
III. Generic Equivalent for Brand:	Metformin HCl Tablets, 500 mg, 500 ct

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	332.4 G		5.325	3.014	16.0496	
Box/ Carton:					0	
Case:	10.8LBS	9.65	6.02	12.87	747.65691	12
Pallet:		47.24	40.5	39.37	75323.4714	72
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer? <input type="text"/>	Size/Strength/Form:	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	500ct/500mg/Tablets		\$39.40			
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Shape:	As of date: <input type="text" value="9/10/2014"/>				
		<input checked="" type="checkbox"/> Each	Product Color:					
		<input type="checkbox"/> Gram	White to off white					
		<input type="checkbox"/> Milliliter	Product Imprint:					
			Z 70					

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No  
RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<b>10368382028058</b>
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/> Box/ Carton	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	
Items aggregated to case?	<input type="text"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	
		<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

### ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic  Inorganic

Antineoplastic  Steroid/Androgen

Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:





# Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

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Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77-064
Rx Product/Proprietary Name:	Metformin HCl Tablets, 500 mg, 1000 ct
NDC:	68382-028-10
CVX Code:	
UPC:	368382028105
MVX Code:	
Description:	White to off-white, round shaped, film-coated tablets debossed with the logo of 'Z' on one side and '70' on the other side.
Active ingredients:	Metformin HCl
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*	
<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:	AB
II. Brand Name:	Glucophage
III. Generic Equivalent for Brand:	Metformin HCl Tablets, 500 mg, 1000 ct

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	647.5 G		7.138	3.678	26.2536	
Box/ Carton:					0	
Case:	19.18LBS	11.34	8.19	15.12	1404.26395	12
Pallet:		47.24	51.57	39.37	95911.8869	36
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer? <input type="text"/>	Size/Strength/Form:	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	1000ct/500mg/Tablets		\$56.95			
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Shape:	As of date: <input type="text" value="9/10/2014"/>				
		<input checked="" type="checkbox"/> Each	Round					
		<input type="checkbox"/> Gram	Product Color:					
		<input type="checkbox"/> Milliliter	White to off white					
			Product Imprint:					
			Z 70					

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No  
RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization							
Serialized?	Yes	Level	How?	RFID	GTIN-14		
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	RFID	<b>10368382028102</b>
If not, when?	<input type="text"/>	Box/Carton	2D	Linear	<input type="checkbox"/>	RFID	<input type="text"/>
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	RFID	<input type="text"/>
		Pallet	2D	Linear	<input type="checkbox"/>	RFID	<input type="text"/>

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

### ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic  Inorganic

Antineoplastic  Steroid/Androgen

Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:





## Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing										
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>										
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing										
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table border="1"><tr><td><input type="checkbox"/></td><td>Monday</td></tr><tr><td><input type="checkbox"/></td><td>Tuesday</td></tr><tr><td><input type="checkbox"/></td><td>Wednesday</td></tr><tr><td><input type="checkbox"/></td><td>Thursday</td></tr><tr><td><input type="checkbox"/></td><td>Friday</td></tr></table> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<input type="checkbox"/>	Monday										
<input type="checkbox"/>	Tuesday										
<input type="checkbox"/>	Wednesday										
<input type="checkbox"/>	Thursday										
<input type="checkbox"/>	Friday										
Class of Trade Restriction:											
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>											
REMS or Registry Restrictions	Return Instructions										
<p><b>REMS:</b> <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>										
<p><b>Registry:</b> <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	ADDITIONAL INFORMATION										
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>										
Other Data Information Required to Process PO:	Miscellaneous Notes:										
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><input type="text"/></p>										