



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:	78-225
Rx Product/Proprietary Name:	Tamsulosin Hydrochloride Capsules, 0.4 mg, 100 ct
NDC:	68382-132-01
UPC:	368382132017
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '2' empty hard gelatin capsules with green colored cap printed with "ZA-18" in black ink and peach colored body printed with "0.4mg" in black ink.
Active ingredients:	Tamsulosin Hydrochloride
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="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
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"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="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:	Flomax
III. Generic Equivalent for Brand:	Tamsulosin Hydrochloride Capsules, 0.4 mg, 100 ct

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 <input type="text" value=""/> If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	51.00 G		3.425	1.878	6.43215	
Box/ Carton:					0	
Case:	4.52LBS	7.52	4.33	11.3	367.94608	24
Pallet:		47.24	47.24	39.37	87858.7849	180
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? <input type="text"/>	Size/Strength/Form: <input type="text" value="100ct/0.4mg/Capsules"/>
(Write-in, e.g. 1 Vial)	Product Shape: <input type="text" value="Capsules"/>
Rx billing unit to pharmacy:	Product Color: <input type="text" value="Green/Peach"/>
<input checked="" type="checkbox"/> Each	Product Imprint: <input type="text" value="ZA18 0.4mg"/>
<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
	\$50.00	
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? 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	10368382132014
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?	<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:	<u>877-993-8779</u>
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<u>www.zydususa.com</u>
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 (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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input style="width: 50%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 50%;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 50%;" type="text"/></p> <p>Fax Number: <input style="width: 50%;" type="text"/></p> <p>Fax Number: <input style="width: 50%;" type="text"/></p> <p>Phone No.: <input style="width: 50%;" type="text"/></p> <p>Site Address: <input style="width: 50%;" type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 50%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" 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 style="width: 50%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50%;" type="text"/></p> <p>Comments: <input style="width: 90%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 50%;" type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 50%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 50%;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 50px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
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 style="width: 90%; height: 40px;" type="text"/></p>	
REMS or Registry Restrictions	Return Instructions
<p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 50%;" 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 style="width: 50%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 50%;" type="text"/></p> <p>DEA #: <input style="width: 50%;" type="text"/></p> <p>PCPDP #: <input style="width: 50%;" type="text"/></p> <p>NPI #: <input style="width: 50%;" type="text"/></p> <p>Comments: <input style="width: 90%; height: 20px;" type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 50%;" type="text"/></p> <p>Comments: <input style="width: 90%; height: 20px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 50%;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 50%;" 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 style="width: 90%; height: 40px;" 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 style="width: 50%;" type="text"/></p> <p>Physician Name: <input style="width: 50%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 50%;" type="text"/></p> <p>Physician State License #: <input style="width: 50%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 50%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 50%;" type="text"/></p>	<p><input style="width: 90%; height: 80px;" type="text"/></p>



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:	78-225
Rx Product/Proprietary Name:	Tamsulosin Hydrochloride Capsules, 0.4 mg, 1000 ct
NDC:	68382-132-10
UPC:	368382132109
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '2' empty hard gelatin capsules with green colored cap printed with "ZA-18" in black ink and peach colored body printed with "0.4mg" in black ink.
Active ingredients:	Tamsulosin Hydrochloride
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="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
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"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	
	<input type="text" value="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:	Flomax
III. Generic Equivalent for Brand:	Tamsulosin Hydrochloride Capsules, 0.4 mg, 1000 ct

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 <input type="text" value=""/> If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	362.00 G		7.138	3.678	26.2536	
Box/ Carton:					0	
Case:	13.72LBS	11.34	8.19	15.12	1404.26395	12
Pallet:		47.24	46.46	39.37	86408.1106	36
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? <input type="text"/>	Size/Strength/Form: <input type="text" value="1000ct/0.4mg/Capsules"/>
(Write-in, e.g. 1 Vial)	Product Shape: <input type="text" value="Capsules"/>
Rx billing unit to pharmacy:	Product Color: <input type="text" value="Green/Peach"/>
<input checked="" type="checkbox"/> Each	Product Imprint: <input type="text" value="ZA18 0.4mg"/>
<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
	\$500.00	
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																																															
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No</p> <p><input type="checkbox"/> Carcinogen</p> <p><input type="checkbox"/> Reproductive Toxicant</p> <p><input type="checkbox"/> Both</p> <p><input type="checkbox"/> Warning appears on label</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #1a3d54; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">Hazardous Waste Identification</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">EPA Hazardous Waste Code:</td> <td style="width: 150px;"></td> </tr> </tbody> </table>	Hazardous Waste Identification		EPA Hazardous Waste Code:																																											
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EPA Hazardous Waste Code:																																															
<p>Is this product regulated for shipment by the DOT? No</p> <p>Is this a reportable quantity? RQ Threshold: <input style="width: 150px;" type="text"/> No</p> <p>Is this a marine pollutant? No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity</p> <p><input type="checkbox"/> Consumer Commodity, ORM-D</p> <p><input type="checkbox"/> Small Quantity (49 CFR 173.4)</p> <p><input type="checkbox"/> Special Permit; DOT-SP</p> <p><input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input style="width: 100px;" type="text"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Cargo</p> <p><input type="checkbox"/> Passenger & Cargo</p>	<p>(if yes, answer a-d below and provide SDS)</p> <p>a. DOT Hazard Class <input style="width: 150px;" type="text"/></p> <p>b. UN/ID Number <input style="width: 150px;" type="text"/></p> <p>c. Packing Group <input style="width: 150px;" type="text"/></p> <p>d. Inhalation Hazard? <input style="width: 150px;" type="text"/></p>																																														
<p style="text-align: center;">ADD'L STORAGE INFORMATION</p> <p>Please check as appropriate for this product.</p> <p><input type="checkbox"/> Organic <input type="checkbox"/> Inorganic</p> <p><input type="checkbox"/> Antineoplastic <input type="checkbox"/> Steroid/Androgen</p> <p><input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer</p> <p><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/></p> <p><input type="checkbox"/> Listed Chemical (List I or II) (Indicate or Write-in below):</p> <p><input type="checkbox"/> Ephedrine</p> <p><input type="checkbox"/> Pseudoephedrine</p> <p><input type="checkbox"/> Phenylpropanolamine</p> <p><input type="checkbox"/> Iodine (≥2.2%)</p> <p><input type="checkbox"/> Other: <input style="width: 150px;" type="text"/></p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #1a3d54; color: white;"> <th colspan="4" style="text-align: center; padding: 2px;">ADDITIONAL PRODUCT INFORMATION - Serialization</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Serialized?</td> <td style="padding: 2px;">Yes</td> <td style="padding: 2px;"><input checked="" type="checkbox"/> Item</td> <td style="padding: 2px;"><input checked="" type="checkbox"/> 2D</td> </tr> <tr> <td style="padding: 2px;">If not, when?</td> <td style="padding: 2px;"><input style="width: 50px;" type="text"/></td> <td style="padding: 2px;"><input checked="" type="checkbox"/> Box/Carton</td> <td style="padding: 2px;"><input checked="" type="checkbox"/> 2D</td> </tr> <tr> <td style="padding: 2px;">Items aggregated to case?</td> <td style="padding: 2px;"><input style="width: 50px;" type="text"/></td> <td style="padding: 2px;"><input checked="" type="checkbox"/> Case</td> <td style="padding: 2px;"><input checked="" type="checkbox"/> 2D</td> </tr> <tr> <td></td> <td></td> <td style="padding: 2px;"><input checked="" type="checkbox"/> Pallet</td> <td style="padding: 2px;"><input checked="" type="checkbox"/> 2D</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #1a3d54; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">REMS or REGISTRY RESTRICTIONS</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Is there a REMS on this product?</td> <td style="padding: 2px;">No</td> </tr> <tr> <td style="padding: 2px;">If Yes, is it managed with a pharmacy registry?</td> <td style="padding: 2px;"><input style="width: 100px;" type="text"/></td> </tr> <tr> <td style="padding: 2px;">Website URL:</td> <td style="padding: 2px;"><input style="width: 150px;" type="text"/></td> </tr> <tr> <td colspan="2" style="padding: 2px;">Comments / Details: (For example, iPledge program?)</td> </tr> <tr> <td colspan="2" style="padding: 2px;"><div style="border: 1px solid black; height: 40px;"></div></td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #1a3d54; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">RETURN INSTRUCTIONS</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Contact tel. # if product received damaged:</td> <td style="padding: 2px;"><input style="width: 150px;" type="text" value="877-993-8779"/></td> </tr> <tr> <td style="padding: 2px;">Is product returnable for credit?</td> <td style="padding: 2px;"><input style="width: 150px;" type="text"/></td> </tr> <tr> <td style="padding: 2px;">URL/Link to returns policy:</td> <td style="padding: 2px;"><input style="width: 150px;" type="text" value="www.zydususa.com"/></td> </tr> <tr> <td style="padding: 2px;">Special regulations or returns requirements for this product in certain states?</td> <td style="padding: 2px;">No</td> </tr> <tr> <td colspan="2" style="padding: 2px;">If so, which states? 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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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____	Purchase order daily receipt cut off time by supplier Cut off time: _____ Shipping lead time of PO: _____ Hours _____ Days Ships same day for next day receipt: <input type="checkbox"/> _____ Ships for second day receipt: <input type="checkbox"/> _____ Ships regular ground for 3-10 days receipt: <input type="checkbox"/> _____
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____	Overnight receipt available: <input type="checkbox"/> _____ PO Receipt cut off time: _____ Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Saturday Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: <input type="checkbox"/> _____ Other fees apply: <input type="checkbox"/> _____
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> _____ Restricted to retail pharmacy only: <input type="checkbox"/> _____ Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> _____ Restricted from US territories? (explain in comments) _____ Comments: _____	
REMS or Registry Restrictions	Return Instructions
REMS: _____ REMS Program Manager Name: _____ Phone: _____ Supplier Manages REMS registry exclusively: <input type="checkbox"/> _____ Wholesale distributor support: <input type="checkbox"/> _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ DEA #: _____ PCPDP #: _____ NPI #: _____ Comments: _____ Registry: _____ Registry Program Contact Name: _____ Phone: _____ Comments: _____	Contact # if product is received damaged: _____ Is product returnable for credit: <input type="checkbox"/> _____ URL/Link to returns policy: _____ Special regulations or returns requirements for this product in certain states? _____ If so, which states? Other requirements? Comments? _____
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Is product order for scheduled patient procedure? <input type="checkbox"/> _____ Is product order for restocking purposes? <input type="checkbox"/> _____ Miscellaneous Notes: _____