

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			intro	auction Type:	New Item		L FII	nal Version		Date:	8/25/	2014
			PRODUCT INFORMATION					SPECIAL HAN	NDLING AND S	TORAGE REQU	UIREMENTS*	
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA							a. Temperature	e – Indicate th	e USP tempera	ture range for	this product.	
	pplication Number for NDA/ANDA/BLA, Med Device: 78040					-, .	I. Freezer – between -25 and -10 C (-13° – 14° F)					
							==			,	,	
	duct/Proprietary Name: Risperidone Tablets, 0.5mg, 60ct						l —		en 2 and 8 C (36	,		
NDC:	68382-113-14			UPC:	368382113146				en 8 and 15 C (4	,		
CVX Code:				MVX Code:			x IV		oom – between 2	,	,	
Description:	red-brown colored, ro	und, biconvex fil	m-coated tablets debossed	with "Z" on one s	side and "6" on other side		l <u> </u>		ursions betweer	`	,	
Active ingredients: Risperidone								. Other Tempe	ive Heat – above rature Range Re	,	·)	1
								(write in)				
URL for Additional Produ		www.zydususa	.com					II. No Requirem				
Address:	73 Route 31 North			Address 2:			b. Contact for	temperature e	excursion quest	ions:		
City:	Pennington		State:	NJ	Zip: 08534		Name:					
Key Contact:			Email:	()			Number:					
Phone Number:	(609) 730 1900		Fax:	(609) 730 199	11		· ·		d to customers of		No	-
		FOR	GENERIC DRUG PRODU	CTS			Is this produc	ct to be shipped	d to customers of	n dry ice?	No	_
I. Orange Book Rating:	AB		II. Brand Name:	Risperdal								
III. Generic Equivalent fo	or Brand:	Risperidone Ta	ablets, 0.5mg, 60ct				c. Special regu	lations for pre	oduct in certair	states?	No	
	DRL	IG SUPPLY CH	AIN SECURITY ACT (DSC:	SA) INFORMATI	ON		Special return	ns requirement	s for this produc	t?	No	•
Does supplier meet DSC			Yes	·	156861945		.,					•
Is product exempt from I		No	165	DONO.	130001943		d. Store produ	ict (unit of cal	a) upright?		Yes	
			<u> </u>				· ·	,	,			-
If yes, select exemption Other exemption - Wri							Protect pro	duct (unit of s	ale) from light?	,	No	
Is product repackaged?		No	If Yes was origin:	al product purch	hased direct from mfr?		e. Shelf life:	24	Months			
.op.oudor.opuonagou.					nasca an cot ironi inii .		c. chich inc.					
	facturer's exclusive d		No No	p. o p o.	nasca an cot from film .		c. Gilon inc.		fe at launch (if	different):		Months
		stributor?			documentation from FDA		c. Gilen inc.			different):		Months
Is product sold by manu		stributor? le?	No	If yes, attach	-		c. Gileii iiic.	Initial shelf li				Months
Is product sold by manu Are any waivers granted	for product ID/barcoo	stributor? le?	No No	If yes, attach	documentation from FDA			Initial shelf li	fe at launch (if	ORMATION	Volume	
Is product sold by manu Are any waivers granted		stributor? le? ADDITIONAL	No No PRODUCT INFORMATION	If yes, attach	documentation from FDA		Weight Lbs.	Initial shelf li	PACKING INF	ORMATION smts.)	Volume (Cube)	Months # Pieces:
Is product sold by manulare any waivers granted Is the Product Legend Device?	for product ID/barcoo	stributor? le? ADDITIONAL	No No PRODUCT INFORMATION Unit of Sale	If yes, attach ORDER INFOR	documentation from FDA		Weight Lbs.	Initial shelf li	PACKING INFormation (IS mensions (US mension	ORMATION smts.) Width:	(Cube)	
Is product sold by manual Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcoo	stributor? le? ADDITIONAL	No No No PRODUCT INFORMATION Unit of Sale X Bottle	If yes, attach	documentation from FDA	Item:		Initial shelf li	PACKING INF	ORMATION smts.)		
Is product sold by manulare any waivers granted Is the Product Legend Device?	for product ID/barcoo	stributor? le? ADDITIONAL No	No No PRODUCT INFORMATION Unit of Sale	If yes, attach ORDER INFOR What is the N	documentation from FDA RMATION IDC selling unit?	Item:	Weight Lbs.	Initial shelf li	PACKING INFormation (IS mensions (US mension	ORMATION smts.) Width:	(Cube) 4.79804	
Is product sold by manual Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcoo	stributor? le? ADDITIONAL No No	No No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	If yes, attach ORDER INFOR What is the N	documentation from FDA		Weight Lbs.	Initial shelf li	PACKING INFormation (IS mensions (US mension	ORMATION smts.) Width:	(Cube)	
Is product sold by manurare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	for product ID/barcoo	stributor? le? ADDITIONAL No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule	If yes, attach ORDER INFOR What is the N	documentation from FDA RMATION IDC selling unit? . 1 Box of 10 Vials)	Box/ Carton:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth	PACKING INF nensions (US m Height 2.982	ormation smts.) Width:	(Cube) 4.79804	# Pieces:
Is product sold by manu- Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	stributor? le? ADDITIONAL No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g.	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes	Box/	Weight Lbs.	Initial shelf li	PACKING INFormation (IS mensions (US mension	ORMATION smts.) Width:	(Cube) 4.79804	
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	Direct Ship Item Direct Control of the state of the stat	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g.	AMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type?	Box/ Carton:	Weight Lbs.	Initial shelf li ITEM AND Dim Depth	PACKING INF nensions (US m Height 2.982	ormation smts.) Width:	(Cube) 4.79804	# Pieces:
Is product sold by manu- Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Control of the state of the stat	stributor? le? ADDITIONAL No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g.	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each	Box/ Carton: Case:	Weight Lbs. 19.09 G 2.34LBS	Initial shelf li ITEM AND Dim Depth 4.06	PACKING INF DPACKING INF Densions (US m Height 2.982	ORMATION smts.) Width: 1.609	(Cube) 4.79804 0 363.574624	# Pieces:
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Control of the state of the stat	stributor? le? ADDITIONAL No No No No No No	No N	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	Weight Lbs. 19.09 G 2.34LBS	Initial shelf li ITEM AND Dim Depth 4.06	PACKING INF DPACKING INF Densions (US m Height 2.982	ORMATION smts.) Width: 1.609	(Cube) 4.79804 0 363.574624	# Pieces:
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Licit Direct Agent?	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g.	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each	Box/ Carton: Case:	Weight Lbs. 19.09 G 2.34LBS	Initial shelf li ITEM AND Dim Depth 4.06	PACKING INF DPACKING INF Densions (US m Height 2.982	ORMATION smts.) Width: 1.609	(Cube) 4.79804 0 363.574624	# Pieces:
Is product sold by manual Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cot Hazardous Material/Cyto Is Item If Unit Dose, is item bar co	Direct Ship Item Direct Ship Item Licit Direct Agent?	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS	Initial shelf li ITEM AND Dim Depth 4.06	PACKING INF nensions (US m Height 2.982 7.76 50.39	ORMATION smts.) Width: 1.609 11.54 39.37	(Cube) 4.79804 0 363.574624	# Pieces:
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance CC Hazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning?	Direct Ship Item Direct Ship Item Licit Direct Agent?	stributor? le? ADDITIONAL No No No No No No	No N	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informate	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INF DPACKING INF Densions (US m Height 2.982	ORMATION smts.) Width: 1.609 11.54 39.37	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manurare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFormation (if processing in the proces	ORMATION smts.) Width: 1.609 11.54 39.37	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces:
Is product sold by manurare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Licit Direct Agent?	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form:	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFO DESCRIPTION OF THE PACKING INFO DESCRIPTION OF TH	ORMATION smts.) Width: 1.609 11.54 39.37 ORMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manurare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFO DESCRIPTION OF THE PACKING INFO DESCRIPTION OF TH	ORMATION smts.) Width: 1.609 11.54 39.37	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets Product Shape: Round, bicon	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFO DESCRIPTION OF THE PACKING INFO DESCRIPTION OF TH	ORMATION smts.) Width: 1.609 11.54 39.37 ORMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manurare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Yes nany of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets Product Shape: Round, bicon	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFO DESCRIPTION OF THE PACKING INFO DESCRIPTION OF TH	ORMATION smts.) Width: 1.609 11.54 39.37 ORMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets Product Shape: Product Color: Red-Brown	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton:	Initial shelf li ITEM AND Dim Depth 4.06 47.24	PACKING INFO DESCRIPTION OF THE PACKING INFO DESCRIPTION OF TH	ORMATION smts.) Width: 1.609 11.54 39.37 ORMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item	stributor? le? ADDITIONAL No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yes many of which package type? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets Product Shape: Product Color: Red-Brown Product Imprint: Z 6	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton: Regular Cost	Initial shelf li ITEM AND Dirr Depth 4.06 47.24 t Per Unit of e (\$)	PACKING INFORMATION (If PACKING INFORMATION (US mensions	ORMATION smts.) Width: 1.609 11.54 39.37 RMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled	Direct Ship Item Direct Ship Item Litic) Direct Ship Item Direct Ship Item State Item Direct Ship Item	Stributor? Ide? ADDITIONAL No No No No No No No Attach copy of SA	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m 1 / BILL UNIT her? 1 Vial) hacy:	documentation from FDA RMATION IDC selling unit? .1 Box of 10 Vials) Ider quantity? Each Inner/Carton/Pack Case Other Product Informat Size/Strength/Form: 60ct/0.5mg/Tablets Product Shape: Product Color: Red-Brown	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 19.09 G 2.34LBS Case: Carton: Regular Cost	Initial shelf li ITEM AND Dirr Depth 4.06 47.24 t Per Unit of e (\$)	PACKING INFORMATION (If PACKING INFORMATION (US mensions	ORMATION smts.) Width: 1.609 11.54 39.37 RMATION st (WAC) (\$)	(Cube) 4.79804 0 363.574624 93717.2771	# Pieces: 24 198



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

N	ATERIAL	. HAZARD CLASSIFICATION an	d TRANSPORT	ATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? d. Does this product require special clean-up instructions?	0	EPA Hazardous Wa		laste Identification				
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	0							
Is this product regulated for shipment by the DOT? Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)	0	(if yes, answer a-d below a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?	·					
Limited Quantity			ADDITIC	NAL PRODUCT IN	FORMATIO	N - Serializatio	on	
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#		Serialized? If not, when? Items aggregated to case?	Yes	Level X Item Box/Carton Case Y Pallet	x 2D x 2D x 2D x 2D x 2D	How? Linear Linear Linear Linear	RFID RFID RFID RFID	GTIN-14 10368382113143
Is the product restricted for air shipment? If so, indicate restriction:				REMS or REGISTR	V DESTRIC	TIONS		
Passenger Cargo Passenger & Cargo ADD'L STORAGE INFORMATION		Is there a REMS on this produc If Yes, is it managed with a p Website URL:	:t? oharmacy registr	y?	T KEOTKIO			
ADD'L STORAGE INFORMATION		Comments / Details: (For exan	iple, iPledge pro	gram?)				
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer								
Aerosol Class; Identify NFPA Storage Level:				RETURN INS	STRUCTION	S		
7 to room oldoo, rachary 11 171 oldrage 2000.		Contact tel. # if product receive	d damaged:	877-993-877				
		Is product returnable for cre						
Listed Chemical (List I or II) (Indicate or Write-in below):		URL/Link to returns policy		www.zydusus	sa.com			
Ephedrine		Special regulations or returns r			in states?		No	_
Pseudoephedrine		If so, which states? Other requ	rements? Comn	nents?				
Phenylpropanolamine								
lodine (≥2.2%)								
Other:								
CLASS OF TRADE RESTRICTION:				ADDITIONAL I	NFORMATI	ON		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	es	If Unit Dose NDC, indicate ND0	C here:					
Restricted to retail pharmacy only:	0		MISCELLAN	NEOUS NOTES and	l/or Image c	f Product Bar	code:	
Restricted to hospital, clinics, and physician offices only:								
Restricted from US territories? (explain in comments)								
Comments:								



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



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			intro	duction Type:	New Iter	n			Final Version		Date:	8/25/	2014
		F	PRODUCT INFORMATION	١					SPECIAL HAI	NDLING AND S	TORAGE REQU	JIREMENTS*	
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.					
Application Number fo			78040	<u> </u>	Аррисацоп.	ANDA			I. Freezer – betw	-	_	-	
											,	,	
Rx Product/Proprietary N		Risperidone Ta	ablets, 0.5mg, 500ct						II. Cold – betwee	,	,		
NDC:	68382-113-05			UPC:	368382113054				III. Cool – betwe	,	,		
CVX Code:				MVX Code:				x	IV. Controlled Ro	oom – between 2	20 and 25 C (68	° – 77° F)	
Description:	red-brown colored, ro	ound, biconvex filr	n-coated tablets debossed	d with "Z" on one s	side and "6" on other side				allows for exc	cursions between	n 15 and 30 C (5	9° – 86° F)	
•	,	,							V. Avoid Excess	ive Heat – above	e 40 C (>104° F)	
Active ingredients: Risperidone								VI. Other Tempe		,			
notice ingredients.								(write in)		'			
URL for Additional Produ	RL for Additional Product Information: www.zydususa.com						, T	VII. No Requiren	nent			<u></u>	
Address:	73 Route 31 North			Address 2:				h Contact fo	or temperature e	vourcion augos	lioner		
City:	Pennington		State:	NJ	Zip : 08534			Name:	i temperature e	xcursion ques	iions.		
Key Contact:	renington		Email:	INJ	21þ.			Number					
Phone Number:	(609) 730 1900		Fax:	(609) 730 199	11				luct to be shipped	d to oustomore s	n ioo?	No	
Filone Number.	(009) 730 1900				71								
		FOR	GENERIC DRUG PRODU	ICTS				is this prod	luct to be shipped	a to customers o	on ary ice?	No	
I. Orange Book Rating:	AB		II. Brand Name:	Risperdal									
III. Generic Equivalent fo	r Brand:	Risperidone Ta	blets, 0.5mg, 500ct					c. Special reg	gulations for pr	oduct in certair	n states?	No	
	DPI	IC SLIBBI V CH	AIN SECURITY ACT (DSC	SA) INFORMATI	ION				urns requirement			No	
			·	· ·				Special rett	ums requirement	is for this produc	λ:	110	
Does supplier meet DSC	SA definition of manu	ıfacturer?	Yes	DUNS:	156861945								
Is product exempt from D	OSCSA?	No						d. Store pro	duct (unit of sa	le) upright?		Yes	
If yes, select exemptio	n.		_					Protect pr	roduct (unit of s	ala) from light	,	No	
Other exemption - Writ								Protect pr	roduct (unit of s	sale) Irom light	f	INO	
•	te in:									-			
Is product repackaged?		No	If Vac was origin	al product purcl	hased direct from mfr?			e. Shelf life:	24	Months			
			_	iai produot paro	nasca an cot nom mm :			c. Onen me.					i
Is product sold by manuf		listributor?	No			_		c. Gilon inc.		ife at launch (if	different):		Months
		listributor?	_		documentation from FDA			c. Gildii ilic.			different):		Months
Is product sold by manuf		listributor? de?	No	If yes, attach				c. chem me.	Initial shelf I				Months
Is product sold by manuf Are any waivers granted	for product ID/barcoo	listributor? de?	No No	If yes, attach	documentation from FDA				Initial shelf li	ife at launch (if	ORMATION	Volume	
Is product sold by manuf Are any waivers granted Is the Product		listributor? de? ADDITIONAL	No No PRODUCT INFORMATION	If yes, attach	documentation from FDA			Weight Lbs.	Initial shelf I	PACKING INF	ORMATION ismts.)	Volume (Cube)	Months # Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device?	for product ID/barcoo	listributor? de? ADDITIONAL	No No PRODUCT INFORMATION Unit of Sale	If yes, attach N ORDER INFOR What is the N	documentation from FDA			Weight Lbs.	Initial shelf li	PACKING INF DEPACKING INF DEPACKING INF DEPACKING INF DEPACKING INFO	ORMATION ssmts.) Width:	(Cube)	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcoo	iistributor? de? ADDITIONAL No No	No No No PRODUCT INFORMATION Unit of Sale X Bottle	If yes, attach	documentation from FDA		Item:		Initial shelf I	PACKING INF	ORMATION ismts.)		
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcoo	istributor? de? ADDITIONAL No No	No No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	If yes, attach ORDER INFOR What is the N Each	documentation from FDA RMATION IDC selling unit?			Weight Lbs.	Initial shelf I	PACKING INF DEPACKING INF DEPACKING INF DEPACKING INF DEPACKING INFO	ORMATION ssmts.) Width:	(Cube) 5.85825	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	for product ID/barcoo	istributor? de? ADDITIONAL No No No No	No No No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule	If yes, attach ORDER INFOR What is the N Each	documentation from FDA		Item: Box/ Carton:	Weight Lbs.	Initial shelf I	PACKING INF DEPACKING INF DEPACKING INF DEPACKING INF DEPACKING INFO	ORMATION ssmts.) Width:	(Cube)	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcoo	istributor? de? ADDITIONAL No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g	documentation from FDA RMATION IDC selling unit? . 1 Box of 10 Vials)	es	Box/ Carton:	Weight Lbs.	Initial shelf li	PACKING INF DPACKING INF nensions (US m Height 3.21	ORMATION usmts.) Width:	(Cube) 5.85825 0	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	Direct Ship Item	istributor? de? ADDITIONAL No No No No	No N	If yes, attach ORDER INFOR What is the N Each	documentation from FDA RMATION IDC selling unit? . 1 Box of 10 Vials)	es	Box/	Weight Lbs.	Initial shelf I	PACKING INF DEPACKING INF DEPACKING INF DEPACKING INF DEPACKING INFO	ORMATION ssmts.) Width:	(Cube) 5.85825	
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	istributor? de? ADDITIONAL No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass	ORDER INFOR What is the N Each (Write-in, e.g	documentation from FDA RMATION IDC selling unit? . 1 Box of 10 Vials)		Box/ Carton: Case:	Weight Lbs.	Initial shelf li ITEM ANE Din Depth 4.21	PACKING INF D PACKING INF Densions (US m Height 3.21	ORMATION Issmts.) Width: 1.825	(Cube) 5.85825 0 197.808534	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti	Direct Ship Item Direct Ship Item	istributor? de? ADDITIONAL No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g	RMATION IDC selling unit? .1 Box of 10 Vials) der quantity? Yelling to the property of the p		Box/ Carton:	Weight Lbs.	Initial shelf li	PACKING INF DPACKING INF nensions (US m Height 3.21	ORMATION usmts.) Width:	(Cube) 5.85825 0	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Controlled Substance Co	Direct Ship Item Direct Ship Item	istributor? de? ADDITIONAL No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g	RMATION RDC selling unit? .1 Box of 10 Vials) der quantity? year quantity? Each		Box/ Carton: Case: Pallet:	Weight Lbs. 44.95 G 2.52LBS	Initial shelf li ITEM ANE Din Depth 4.21	PACKING INF D PACKING INF Densions (US m Height 3.21	ORMATION Issmts.) Width: 1.825	(Cube) 5.85825 0 197.808534	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcoti Controlled Substance Controlled Substance Co	Direct Ship Item Direct Ship Item	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the N Each (Write-in, e.g	RMATION IDC selling unit? . 1 Box of 10 Vials) der quantity? year		Box/ Carton: Case:	Weight Lbs.	Initial shelf li ITEM ANE Din Depth 4.21	PACKING INF D PACKING INF Densions (US m Height 3.21	ORMATION Issmts.) Width: 1.825	(Cube) 5.85825 0 197.808534	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Co Hazardous Material/Cyto Is Item	Direct Ship Item Direct Ship Item ic) ide: toxic Agent?	istributor? de? ADDITIONAL No No No No No	No N	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g Minimum ord If Yes, how m	AMATION ADC selling unit? . 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack		Box/ Carton: Case: Pallet:	Weight Lbs. 44.95 G 2.52LBS	Initial shelf li ITEM ANE Din Depth 4.21	PACKING INF D PACKING INF Densions (US m Height 3.21	ORMATION Issmts.) Width: 1.825	(Cube) 5.85825 0 197.808534	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Control	Direct Ship Item Direct Ship Item ic) ide: toxic Agent?	istributor? de? ADDITIONAL No No No No No	No N	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g Minimum ord If Yes, how m	AMATION ADC selling unit? . 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case	e? 	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS	Initial shelf li ITEM ANE Din Depth 4.21	PACKING INF DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24	ORMATION (Semts.) Width: 1.825 7.91 39.37	(Cube) 5.85825 0 197.808534	# Pieces:
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	Direct Ship Item Direct Ship Item ic) ide: toxic Agent?	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER	ORDER INFORMATION ORDER INFORMATION What is the Normation Each (Write-in, e.g. Minimum ord If Yes, how many the second of the second order in the second order i	AMATION ADC selling unit? . 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product In	e? 	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf li ITEM ANE Din Depth 4.21 47.24	PACKING INF D PACKING INF Densions (US m Height 3.21	ORMATION (Semts.) Width: 1.825 7.91 39.37	(Cube) 5.85825 0 197.808534 87858.7849	# Pieces: 12 208
Is product sold by manuf Are any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Control	Direct Ship Item Direct Ship Item ic) ide: toxic Agent?	istributor? de? ADDITIONAL No No No No No	No N	ORDER INFORMATION ORDER INFORMATION What is the Normation Each (Write-in, e.g. Minimum ord If Yes, how many the second of the second order in the second order i	AMATION ADC selling unit? .1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product In Size/Strength/Form:	e? 	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	PACKING INFormation (if a transfer at launch (if packing information) (US market) (IS mark	ORMATION (Semts.) Width: 1.825 7.91 39.37	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controll	Direct Ship Item Direct Ship Item ic) ic) ide: toxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor	ORDER INFORMATION What is the NEach (Write-in, e.g. Minimum ord If Yes, how means the second of the	AMATION ADC selling unit? . 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product In	e? 	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf li ITEM ANE Din Depth 4.21 47.24	PACKING INFormation (if a transfer at launch (if packing information) (US market) (IS mark	ORMATION (smts.) (width: 1.825 7.91 39.37	(Cube) 5.85825 0 197.808534 87858.7849	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controll	Direct Ship Item Direct Ship Item ic) ide: toxic Agent?	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g.	ORDER INFORMATION What is the NEACH (Write-in, e.g. Minimum order of the New York (Write-in, e.g. Minimum order of	documentation from FDA RMATION RDC selling unit? .1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product In Size/Strength/Form: [500ct/0.5mg/Tablets	e? 	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24 COST INFO Invoice Co	ORMATION Ismts.) Width: 1.825 7.91 39.37 ORMATION Ist (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controll	Direct Ship Item Direct Ship Item ic) ic) ide: toxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor	ORDER INFORMATION What is the NEACH (Write-in, e.g. Minimum order of the New York (Write-in, e.g. Minimum order of	documentation from FDA RMATION RDC selling unit? .1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product In Size/Strength/Form: [500ct/0.5mg/Tablets	aformation	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24 COST INFO Invoice Co	ORMATION (smts.) (width: 1.825 7.91 39.37	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controll	Direct Ship Item Direct Ship Item ic) ic) ide: toxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g.	ORDER INFORMATION What is the NEACH (Write-in, e.g. Minimum order of the New York (Write-in, e.g. Minimum order of	AMATION ADC selling unit? In Box of 10 Vials) Ser quantity? Each Inner/Carton/Pack Case Other Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Shape: Rounce	aformation	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24 COST INFO Invoice Co	ORMATION Ismts.) Width: 1.825 7.91 39.37 ORMATION Ist (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Controll	Direct Ship Item Direct Ship Item ic) ic) ide: toxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No	No N	ORDER INFORMATION What is the NEACH (Write-in, e.g. Minimum order of the New York (Write-in, e.g. Minimum order of	AMATION ADC selling unit? In Box of 10 Vials) Ser quantity? Each Inner/Carton/Pack Case Other Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Shape: Rounce	aformation	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24 COST INFO Invoice Co	ORMATION Ismts.) Width: 1.825 7.91 39.37 ORMATION Ist (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Cothazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item ic) ic) ide: toxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No	No No No No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In PHARMACY ORDER Rec. sell unit to custor (Write-in, e.g. Rx billing unit to pharm x Each	ORDER INFORMATION What is the NEACH (Write-in, e.g. Minimum order of the New York (Write-in, e.g. Minimum order of	AMATION ADC selling unit? .1 Box of 10 Vials) der quantity? .2 Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Color: Red-B	aformation	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton:	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of	DPACKING INF DPACKING INF Densions (US m Height 3.21 5.94 47.24 COST INFO Invoice Co	ORMATION Ismts.) Width: 1.825 7.91 39.37 ORMATION Ist (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Cothazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item Lic) Ide: Location Agent? Direct Ship Item SALER USE ONLY:	istributor? de? ADDITIONAL No No No No No No	No N	ORDER INFORMATION ORDER INFORMATION What is the Normation Each (Write-in, e.g Minimum ord If Yes, how normation 1 Vial) Macy:	AMATION ADC selling unit? .1 Box of 10 Vials) der quantity? .1 Box of 10 Vials) der quantity? .1 Box of 10 Vials) der quantity? .2 Case Other Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Shape: Product Color: Product Imprint: Z 6	d, biconvex	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton: Regular Co	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of ale (\$)	PACKING INFORMATION OF THE PACKING INFORMATION O	ORMATION (smts.) Width: 1.825 7.91 39.37 PRMATION (st (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Cothazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item Lic) Ide: Location Agent? Direct Ship Item SALER USE ONLY:	istributor? de? ADDITIONAL No No No No No No	No N	ORDER INFORMATION ORDER INFORMATION What is the Normation Each (Write-in, e.g Minimum ord If Yes, how normation 1 Vial) Macy:	AMATION ADC selling unit? .1 Box of 10 Vials) der quantity? .2 Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Color: Red-B	d, biconvex	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton: Regular Co	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of ale (\$)	PACKING INFORMATION OF THE PACKING INFORMATION O	ORMATION (smts.) Width: 1.825 7.91 39.37 PRMATION (st (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208
Is product sold by manufare any waivers granted Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic Controlled Substance Cothazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item Lic) Ici) Ide: Itoxic Agent? ded to unit dose for	istributor? de? ADDITIONAL No No No No No No Additional No No Additional Attach copy of SA	No N	If yes, attach ORDER INFOR What is the N Each (Write-in, e.g Minimum ord If Yes, how n 1 1 Vial) macy:	AMATION ADC selling unit? .1 Box of 10 Vials) der quantity? .1 Box of 10 Vials) der quantity? .1 Box of 10 Vials) der quantity? .2 Case Other Product In Size/Strength/Form: 500ct/0.5mg/Tablets Product Shape: Product Color: Product Imprint: Z 6	of ormation of the convex of t	Box/ Carton: Case: Pallet: UPC:	Weight Lbs. 44.95 G 2.52LBS Case: Carton: Regular Co	Initial shelf II ITEM AND Din Depth 4.21 47.24 Dost Per Unit of ale (\$)	PACKING INFORMATION OF THE PACKING INFORMATION O	ORMATION (smts.) Width: 1.825 7.91 39.37 PRMATION (st (WAC) (\$)	(Cube) 5.85825 0 197.808534 87858.7849 Federal Exc	# Pieces: 12 208



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

	MATERIAL	$_{ t L}$ HAZARD CLASSIFICATION an	d TRANSPORT	ATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? d. Does this product require special clean-up instructions?	No No No	EPA Hazardous Was		aste Identification				
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No							
Is this product regulated for shipment by the DOT? Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)	No No	(if yes, answer a-d below a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?	and provide SDS)				
Limited Quantity			ADDITIO	NAL PRODUCT INF	ORMATION	I - Serializatio	on	
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#		Serialized? If not, when? Items aggregated to case?	Yes	Level X Item X Box/Carton X Case X Pallet	x 2D x 2D x 2D x 2D x 2D	How? Linear Linear Linear Linear	RFID RFID RFID RFID	GTIN-14 10368382113051
Is the product restricted for air shipment? If so, indicate restriction:				REMS or REGISTRY	DESTRICT	IONS		
Passenger Cargo Passenger & Cargo ADD'L STORAGE INFORMATION		Is there a REMS on this product If Yes, is it managed with a product Website URL:	:t? harmacy registry	No No	NEOTHIO!	iono		
ADD'L STORAGE INFORMATION		Comments / Details: (For exam	ipie, iPieage prog	gram?)				
Please check as appropriate for this product. Organic Inorganic Steroid/Androgen Corrosive Oxidizer								
Aerosol Class; Identify NFPA Storage Level:				RETURN INST	RUCTIONS	:		
Acrosol Class, Identity NFF A Storage Level.		Contact tel. # if product receive	d damaged:	877-993-8779		,		
		Is product returnable for cred		011 000 0110				
Listed Chemical (List I or II) (Indicate or Write-in below):		URL/Link to returns policy		www.zydususa	a.com			
Ephedrine		Special regulations or returns re	equirements for t	his product in certain	states?		No	
Pseudoephedrine		If so, which states? Other requi	rements? Comm	ents?				
Phenylpropanolamine								
Iodine (≥2.2%)								
Other:								
CLASS OF TRADE RESTRICTION:				ADDITIONAL IN	FORMATIC	ON		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	If Unit Dose NDC, indicate ND0	C here:					
Restricted to retail pharmacy only:	No	2 2000 1120,		EOUS NOTES and/o	or Image of	Product Bar	code:	
			MIGOLLEAN	LOGO NOTEO arta/C	J. IIIIage OI	- Todact Ball		
Restricted to hospital, clinics, and physician offices only:	No							
Restricted from US territories? (explain in comments)	No							
Comments:								



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