

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014	Introduction Type: New Item							Fir	nal Version		Date:	8/25/	2014
		F	RODUCT INFORMATION						SPECIAL HAN	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 for			77-837	ļ	7.66	,	•		Freezer – betw	een -25 and -10	C (-13° – 14° F	5)	
Rx Product/Proprietary N			blets, 10 mg, 90ct							n 2 and 8 C (36	,	,	
NDC:	68382-066-16	Omitvaotatii Ta	bioto, 10 mg, coot	UPC:	368382066169					en 8 and 15 C (4	,		
CVX Code:	***************************************									oom – between 2	,	° – 77° F)	
Description:	Pink oval shaped his	convex heveled	edge, film-coated tablets in	norinted with '743	20' in black ink on one si	side and plain or	the other			ursions between	,	,	
Description.	side.	sorrex, beveled t	sage, min coated tablets in	ipinited with 2A2	EO III DIACK IIIK OII OIIC 3	side and plain of	THE OHIE	□ v.		ive Heat – above	,		
Active ingredients:		Simvastatin								rature Range Re	,	,	
									(write in)		·		
URL for Additional Produ	uct Information:	www.zydususa	.com					VI	II. No Requirem	nent			
Address:	73 Route 31 North			Address 2:				b. Contact for	temperature e	excursion quest	tions:		
City:	Pennington		State:	NJ	Zip:	08534		Name:					
Key Contact:	(000) =00 1000		Email:	(222) =22 42				Number:					
Phone Number:	(609) 730 1900		Fax:	(609) 730 199) 1					d to customers o		No	
		FOR	GENERIC DRUG PRODU	CTS				Is this produc	ct to be shipped	d to customers of	on dry ice?	No	
I. Orange Book Rating:	AB		II. Brand Name:	Zocor									
III. Generic Equivalent fo	r Brand:	Simvastatin Ta	blets, 10 mg, 90ct					c. Special regu	lations for pr	oduct in certair	n states?	No	
	DRU	JG SUPPLY CHA	AIN SECURITY ACT (DSC:	SA) INFORMATI	ION			Special return	ns requirement	s for this produc	t?	No	
Does supplier meet DSC	SA definition of manu	facturer?	Yes	DUNS:	156861945								
Is product exempt from I		No						d. Store produ	uct (unit of sal	e) upright?		Yes	
If yes, select exemption			_					•	,	ale) from light	,	No	
Other exemption - Wri								1 Total pro-	auct (annt or s	ale, Holli light		140	
Is product repackaged?		No	If Voc was origin	al product pure	hased direct from mfr	.2		e. Shelf life:	24	Months			
		140	ii ies, was ongin	ai product purc	naseu un ect nom min	1 :		e. Sileli ille.	24	WOULD			
	lacturer's exclusive d	istributor?	No						Initial shelf li	fe at launch (if	different):		Months
Are any waivers granted	facturer's exclusive d for product ID/barco		No No	If yes, attach	documentation from	FDA			Initial shelf li	fe at launch (if	different):		Months
		ie?	No		documentation from	FDA				,	,		Months
Are any waivers granted	for product ID/barcoo	ie?		N		FDA			ITEM AND	PACKING INF	ORMATION	Volume	
Are any waivers granted Is the Product		de? ADDITIONAL	No PRODUCT INFORMATION	ORDER INFOR	RMATION	FDA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION ismts.)	Volume (Cube)	Months # Pieces:
Are any waivers granted	for product ID/barcoo	ie?	No	ORDER INFOR		FDA		1	ITEM AND	PACKING INF nensions (US m Height	ORMATION ismts.) Width:	(Cube)	
Is the Product Legend Device?	for product ID/barcoo	ADDITIONAL	No PRODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION	FDA	Item:	Weight Lbs.	ITEM AND	PACKING INF	ORMATION ismts.)		
Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcoo	ADDITIONAL No No No No	No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule	ORDER INFOR	RMATION	FDA	Box/	1	ITEM AND	PACKING INF nensions (US m Height	ORMATION ismts.) Width:	(Cube) 4.88538	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	for product ID/barcoo	ADDITIONAL No No No	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass	ORDER INFORMATION ORDER INFORM	RMATION NDC selling unit? 1. 1 Box of 10 Vials)			1	ITEM AND	PACKING INF nensions (US m Height	ORMATION ismts.) Width:	(Cube)	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	ADDITIONAL No No No No	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube	ORDER INFOR	RMATION NDC selling unit? 1. 1 Box of 10 Vials)	FDA Yes	Box/	1	ITEM AND	PACKING INF nensions (US m Height	ORMATION ismts.) Width:	(Cube) 4.88538	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	ADDITIONAL No No No No	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFORMATION What is the MEach (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity?	Yes	Box/ Carton:	27.00 G	Dim Depth	D PACKING INF nensions (US m Height 3.025	ORMATION usmts.) Width:	(Cube) 4.88538	#Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	NO NO NO NO NO	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFORMATION What is the MEach (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) ther quantity? nany of which package	Yes	Box/ Carton:	27.00 G	Dim Depth	PACKING INF nensions (US m Height 3.025	ORMATION usmts.) Width:	(Cube) 4.88538	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	ADDITIONAL No No No No	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFORMATION What is the MEach (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity?	Yes	Box/ Carton: Case: Pallet:	27.00 G	Dim Depth	D PACKING INF nensions (US m Height 3.025	ORMATION Issmts.) Width: 1.615	(Cube) 4.88538 0 363.574624	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	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 INFORMATION What is the MEach (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity? nany of which package Each	Yes	Box/ Carton: Case:	27.00 G 2.86LBS	Dim Depth	D PACKING INF nensions (US m Height 3.025	ORMATION Issmts.) Width: 1.615	(Cube) 4.88538 0 363.574624	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc	Direct Ship Item Direct Ship Item ic) de: toxic Agent?	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	ORDER INFORMATION What is the MEach (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) ther quantity? nany of which package Each Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	27.00 G 2.86LBS Case:	Dim Depth	D PACKING INF nensions (US m Height 3.025	ORMATION Issmts.) Width: 1.615	(Cube) 4.88538 0 363.574624	# Pieces:
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	Direct Ship Item Direct Ship Item ic) de: toxic Agent?	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	ORDER INFORMATION What is the MEach (Write-in, e.g Minimum ord If Yes, how n	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case	Yes	Box/ Carton: Case: Pallet: UPC:	27.00 G 2.86LBS Case:	Dim Depth	D PACKING INF nensions (US m Height 3.025	ORMATION Usimts.) Width: 1.615 11.54 39.37	(Cube) 4.88538 0 363.574624	# Pieces:
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Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	Direct Ship Item Direct Ship Item ic) de: toxic Agent?	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 custon	ORDER INFORMATION What is the MEach (Write-in, e.g Minimum ord If Yes, how n 1	RMATION NDC selling unit? 1. 1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case Other Prod	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	27.00 G 2.86LBS Case: Carton:	Dim Depth 7.76 47.24	PACKING INF Densions (US m Height 3.025 4.06 50.39	ORMATION Usimts.) Width: 1.615 11.54 39.37	(Cube) 4.88538 0 363.574624 93717.2771	# Pieces: 24 144
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Is the Product Legend Device? State Control? ARCOS reportable? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item ic) ode: toxic Agent?	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 custon (Write-in, e.g. Rx billing unit to pharm X Each	ORDER INFORM What is the N Each (Write-in, e.g Minimum ord If Yes, how n 1 / BILL UNIT mer? 1 Vial)	RMATION NDC selling unit? 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Prod Size/Strength/Form 90ct/10mg/Tablets Product Shape: Product Color:	Yes ge type? duct Information: Oval Pink	Box/ Carton: Case: Pallet: UPC:	27.00 G 2.86LBS Case: Carton:	Dim Depth 7.76 47.24	PACKING INFORMATION (US mensions (US mension	ORMATION Usints.) Width: 1.615 11.54 39.37 ORMATION Ust (WAC) (\$)	(Cube) 4.88538 0 363.574624 93717.2771	# Pieces: 24 144
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	AL HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen	<u>-</u> -	
Reproductive Toxicant Both Warning appears on label	Hazardous Waste Identification	
c. Contact Hazard?	EPA Hazardous Waste Code:	
d. Does this product require special clean-up instructions?		
(If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	-	
Is this product regulated for shipment by the DOT?	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class	
Is this a reportable quantity?	b. UN/ID Number	
RQ Threshold:	c. Packing Group	
Is this a marine pollutant? No	d. Inhalation Hazard?	
Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)		
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization	
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	Level	66166
Special Permit; DOT-SP	If not, when? X Box/Carton X 2D Linear RFID RFID	00100
Special Provision (listed in Column 7 of 49 CFR 172.101);	Items aggregated to case?	
SP#	x Pallet x 2D Linear RFID	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)	
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	
Listed Chemical (List I or II) (Indicate or Write-in below):	Is product returnable for credit: URL/Link to returns policy: www.zydususa.com	
Ephedrine		
	Special regulations or returns requirements for this product in certain states?	
Pseudoephedrine	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?	
l <u> </u>		
Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%)		
Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other:	If so, which states? Other requirements? Comments?	
Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%)	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION	
Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other:	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:	
Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other: CLASS OF TRADE RESTRICTION:	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION	
Pseudoephedrine Phenylpropanolamine lodine (22.2%) Other: CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:	
Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other: CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:	
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Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other: CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:	



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	Introduction Type: New Item							Fir	nal Version		Date:	8/25/	2014
		P	RODUCT INFORMATION						SPECIAL HAN	NDLING AND S	TORAGE REQI	JIREMENTS*	
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA						Δ	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for			77-837		7 tpp://dui.orm	,	•		Freezer – betw	reen -25 and -10) C (-13° – 14° F	- F)	
Rx Product/Proprietary N			blets, 10 mg, 500ct					==		n 2 and 8 C (36	,	,	
NDC:	68382-066-05	Omit dotatin Ta	blots, 10 mg, cocot	UPC:	368382066053					en 8 and 15 C (4	,		
CVX Code:	· · · · · · · · · · · · · · · · · · ·									,	20 and 25 C (68	° – 77° F)	
Description:	Pink oval shaped his	convex heveled a	edge, film-coated tablets im	nrinted with '742	20' in black ink on one	side and plain or	n the other				n 15 and 30 C (5	,	
Description.	side.	orivex, beveled t	ouge, min coated tablets in	iprinted with ZAZ	EO III DIACK IIIK OII OIIC	side and plain of	THE OTHER	│			e 40 C (>104° F	,	
Active ingredients:		Simvastatin								rature Range R	,	,	
_									(write in)	Ĭ.	·		
URL for Additional Produ	uct Information:	www.zydususa.	com					VI	I. No Requirem	nent			
Address:	73 Route 31 North			Address 2:				b. Contact for	temperature e	xcursion ques	tions:		
City:	Pennington		State:	NJ	Zip:	08534		Name:					
Key Contact:	(000) =00 (000		Email:	(000) =00 (000)				Number:					
Phone Number:	(609) 730 1900		Fax:	(609) 730 199) 1					to customers of		No	
		FOR	GENERIC DRUG PRODU	стѕ				Is this produc	ct to be shipped	d to customers of	on dry ice?	No	
I. Orange Book Rating:	AB		II. Brand Name:	Zocor									
III. Generic Equivalent fo	r Brand:	Simvastatin Ta	blets, 10 mg, 500ct					c. Special regu	lations for pro	oduct in certaiı	n states?	No	
	DRU	IG SUPPLY CHA	IN SECURITY ACT (DSC	SA) INFORMATI	ION			Special return	ns requirement	s for this produc	ct?	No	
Does supplier meet DSC	SA definition of manu	facturer?	Yes	DUNS:	156861945								
Is product exempt from I		No					<u> </u>	d. Store produ	uct (unit of sal	e) upright?		Yes	
If yes, select exemption			_					•	•	ale) from light	?	No	
Other exemption - Wri						7		Trotect pro-	duct (dilit of 3	aic) iroin iigiit	•	140	
Is product repackaged?		No	If Voc was origin	al product purc	hased direct from mf	-l fr?		e. Shelf life:	24	Months			
Is product repackaged:	facturaria avaluativa d		ii ies, was origini	ai product purci	naseu un ect nom mi	11 :		e. Sileli ille.	24	WIOTILIS			
		stributor?	No						Initial shelf li	fe at launch (if	different):		Months
Are any waivers granted			No No	If yes, attach	documentation from	n FDA			Initial shelf li	fe at launch (if	different):		Months
		le?	No		documentation from	n FDA				,	,		Months
Are any waivers granted	for product ID/barcoo	le?		l ·		n FDA			ITEM AND	PACKING INF	ORMATION	Volume	
Are any waivers granted Is the Product		le? ADDITIONAL I	No PRODUCT INFORMATION	ORDER INFOR	RMATION	n FDA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION nsmts.)	Volume (Cube)	Months # Pieces:
Are any waivers granted	for product ID/barcoo	le?	No	ORDER INFOR		n FDA			ITEM AND	PACKING INF nensions (US m Height	ORMATION nsmts.) Width:	(Cube)	
Is the Product Legend Device?	for product ID/barcoo	ADDITIONAL I	No PRODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION	n FDA	Item:	Weight Lbs.	ITEM AND	PACKING INF	ORMATION nsmts.)		
Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcoo	NO NO NO	No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton Ampule	ORDER INFOR	RMATION	n FDA	Box/		ITEM AND	PACKING INF nensions (US m Height	ORMATION nsmts.) Width:	(Cube) 6.43215	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	for product ID/barcoo	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	RMATION NDC selling unit?				ITEM AND	PACKING INF nensions (US m Height	ORMATION nsmts.) Width:	(Cube)	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct Ship Item	NO NO NO	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube	ORDER INFOR	RMATION NDC selling unit?	n FDA	Box/		ITEM AND	PACKING INF nensions (US m Height	ORMATION nsmts.) Width:	(Cube) 6.43215	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item	NO NO NO	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFOR What is the N Each (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity?	Yes	Box/ Carton: Case:	75.00 G	Dim Depth	PACKING INF nensions (US m Height 3.425	ORMATION DESMITS.) Width: 1.878	(Cube) 6.43215 0 254.35755	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	NO NO NO	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N Each (Write-in, e.g	RMATION NDC selling unit?	Yes	Box/ Carton:	75.00 G	Depth	PACKING INF nensions (US m Height 3.425	ORMATION nsmts.) Width:	(Cube) 6.43215	#Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	NO NO NO NO	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFOR What is the N Each (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity? nany of which package	Yes	Box/ Carton: Case: Pallet:	75.00 G	Dim Depth	PACKING INF nensions (US m Height 3.425	ORMATION DESMITS.) Width: 1.878	(Cube) 6.43215 0 254.35755	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	Direct Ship Item Direct Ship Item	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 NDC selling unit? 1. 1 Box of 10 Vials) Der quantity? The package of th	Yes	Box/ Carton: Case:	75.00 G 3.30LBS	Dim Depth	PACKING INF nensions (US m Height 3.425	ORMATION DESMITS.) Width: 1.878	(Cube) 6.43215 0 254.35755	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent?	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	ORDER INFOR What is the N Each (Write-in, e.g	RMATION NDC selling unit? 1. 1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack	Yes	Box/ Carton: Case: Pallet:	75.00 G 3.30LBS	Dim Depth	PACKING INF nensions (US m Height 3.425	ORMATION DESMITS.) Width: 1.878	(Cube) 6.43215 0 254.35755	# Pieces:
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	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent?	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	ORDER INFOR What is the M Each (Write-in, e.g Minimum ord If Yes, how n	RMATION NDC selling unit? I. 1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case	Yes	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS	Dim Depth	PACKING INF nensions (US m Height 3.425	ORMATION DISMITS.) Width: 1.878 8.7 39.37	(Cube) 6.43215 0 254.35755	# Pieces:
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Collarardous Material/Cyto	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent?	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	ORDER INFORM What is the M Each (Write-in, e.g Minimum ord If Yes, how m	RMATION NDC selling unit? 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Form	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INF Densions (US m Height 3.425 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning?	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent?	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 custon	ORDER INFOR What is the N Each (Write-in, e.g Minimum ord If Yes, how m	RMATION NDC selling unit? 1. 1 Box of 10 Vials) Ider quantity? Inany of which package Each Inner/Carton/Pack Case Other Pro	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INF Densions (US m Height 3.425 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled Substa	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent?	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 INFOR What is the N Each (Write-in, e.g Minimum ord If Yes, how m	RMATION NDC selling unit? 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Form	Yes ge type?	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INF Densions (US m Height 3.425 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Controlled Substa	Direct Ship Item Direct Ship Item ic) ode: otoxic Agent?	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 custon	ORDER INFORM What is the M Each (Write-in, e.g Minimum ord If Yes, how m 1 / BILL UNIT	RMATION NDC selling unit? 1. 1 Box of 10 Vials) ther quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr 500ct/10mg/Tablets	Yes lige type? oduct Information: s	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INFORMATION (US many Height 3.425) 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
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? Is it reverse numbered?	Direct Ship Item Direct Ship Item ic) ode: otoxic Agent?	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 custom (Write-in, e.g.	ORDER INFORM What is the M Each (Write-in, e.g Minimum ord If Yes, how m 1 / BILL UNIT	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr 500ct/10mg/Tablets Product Shape:	Yes lige type? oduct Information m: s Oval Pink	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INFORMATION (US many Height 3.425) 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37 DRMATION DISMITS (WAC) (\$)	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
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 cohospital scanning? Is it reverse numbered? WHOLE Vendor #:	Direct Ship Item Direct Ship Item ic) ode: otoxic Agent?	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 custon (Write-in, e.g. Rx billing unit to pharm X Each Gram	ORDER INFORM What is the M Each (Write-in, e.g Minimum ord If Yes, how m 1 / BILL UNIT	RMATION NDC selling unit? 1. 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr 500ct/10mg/Tablets Product Shape:	Yes lige type? oduct Information m: s Oval	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INFORMATION OF THE PROPERTY OF THE PRO	ORMATION Insmts.) Width: 1.878 8.7 39.37 ORMATION Dist (WAC) (\$)	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item ic) ode: otoxic Agent?	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 custon (Write-in, e.g. Rx billing unit to pharm X Each	ORDER INFORM What is the M Each (Write-in, e.g Minimum ord If Yes, how m 1 / BILL UNIT	RMATION NDC selling unit? 1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Fort 500ct/10mg/Tablets Product Shape: Product Color:	Yes lige type? oduct Information m: s Oval Pink	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton:	Dim Depth 6.57 47.24 t Per Unit of	PACKING INFORMATION (US many Height 3.425) 4.45 46.46 COST INFO	ORMATION DISMITS.) Width: 1.878 8.7 39.37 DRMATION DISMITS (WAC) (\$)	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item ic) ode: ctoxic Agent? ded to unit dose for	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 custon (Write-in, e.g. Rx billing unit to pharm X Each Gram	ORDER INFOR What is the M Each (Write-in, e.g Minimum ord If Yes, how n 1 / BILL UNIT ner? 1 Vial) nacy:	RMATION NDC selling unit? 1.1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr 500ct/10mg/Tablets Product Shape: Product Color: Product Imprint:	Yes Inge type? I	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton: Regular Cost Sale	Dim Depth 6.57 47.24 t Per Unit of e (\$)	PACKING INF Densions (US m Height 3.425 4.45 46.46 COST INFO Invoice Co	ORMATION Insmts.) Width: 1.878 8.7 39.37 ORMATION Dist (WAC) (\$)	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per
Is the Product Legend Device? State Control? ARCOS reportable? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? Is it reverse numbered? WHOLE Vendor #: Whsl. Code #:	Direct Ship Item Direct Ship Item ic) ode: stoxic Agent? SALER USE ONLY:	No N	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 custon (Write-in, e.g. Rx billing unit to pharm x Each Gram Milliliter	ORDER INFOR What is the M Each (Write-in, e.g Minimum ord If Yes, how m 1 A BILL UNIT mer? 1 Vial) nacy:	RMATION NDC selling unit? 1.1 Box of 10 Vials) der quantity? nany of which package Each Inner/Carton/Pack Case Other Pro Size/Strength/Forr 500ct/10mg/Tablets Product Shape: Product Color: Product Imprint:	Yes Inge type? Oval Pink ZA 20 ERT, LABEL AN	Box/ Carton: Case: Pallet: UPC:	75.00 G 3.30LBS Case: Carton: Regular Cost Sale	Dim Depth 6.57 47.24 t Per Unit of e (\$)	PACKING INF Densions (US m Height 3.425 4.45 46.46 COST INFO Invoice Co	ORMATION Insmts.) Width: 1.878 8.7 39.37 ORMATION Dist (WAC) (\$)	(Cube) 6.43215 0 254.35755 86408.1106	# Pieces: 12 126 ise Tax Per



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIA	IAL HAZARD CLASSIFICATION and TRANSPORTATION	
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	Hazardous Waste Identification EPA Hazardous Waste Code:	
(If yes, attach SDS with special instructions.) e. Does the product require special clean-up instructions.) 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)	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?	
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization	
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#	Level How? GTIN-14	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)	
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	
T Tristed Chemical (Fist For II) (Indicate of Write-In below).	Is product returnable for credit: URL /Link to returns policy: www.zydususa.com	
Listed Chemical (List I or II) (Indicate or Write-in below): Ephedrine Pseudoephedrine Desider reported in a	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	
Ephedrine Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?	
Ephedrine Pseudoephedrine Phenylpropanolamine lodine (≥2.2%)	URL/Link to returns policy: www.zydususa.com Special regulations or returns requirements for this product in certain states? No	
Ephedrine Pseudoephedrine Phenylpropanolamine lodine (≥2.2%) Other:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?	
Ephedrine Pseudoephedrine Phenylpropanolamine Iodine (≥2.2%) Other: CLASS OF TRADE RESTRICTION:	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION	
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	URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here:	



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	Introduction Type: New Item							Fi	nal Version		Date:	8/25/	2014
		F	PRODUCT INFORMATION						SPECIAL HAN	NDLING AND S	TORAGE REQI	JIREMENTS*	
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA						A	a. Temperature	e – Indicate th	e USP tempera	ture range for	this product.		
Application Number fo			77-837					I.	Freezer – betw	een -25 and -10	C (-13° – 14° F	-)	
Rx Product/Proprietary N	Name:	Simvastatin Ta	blets, 10 mg, 1000ct						Cold – betwee	n 2 and 8 C (36	° – 46° F)		
NDC:	68382-066-10		3 ,	UPC:	368382066107					en 8 and 15 C (4	,		
CVX Code:	***************************************							x IV	. Controlled Ro	oom – between 2	20 and 25 C (68	° – 77° F)	
Description:	Pink, oval shaped, bi	iconvex, beveled	edge, film-coated tablets im	printed with 'ZA2	20' in black ink on one	side and plain or	n the other		allows for exc	ursions between	n 15 and 30 C (5	59° – 86° F)	
	side.	•	•	•		•		V.	Avoid Excessi	ive Heat – above	e 40 C (>104° F)	
Active ingredients:		Simvastatin						VI		rature Range Re	equirement		i
									(write in)				
URL for Additional Produ		www.zydususa	.com					L vi	II. No Requirem	nent			
Address:	73 Route 31 North			Address 2:		1		b. Contact for	temperature e	excursion quest	tions:		
City:	Pennington		State: Email:	NJ	Zip:	08534		Name:					
Key Contact: Phone Number:	(609) 730 1900		Fax:	(609) 730 199	21			Number:	et to be shipped	d to customers o	on ice?	No	
Filone Number.	(003) 730 1300	FOR		` '	, i					d to customers of			
		FUR	GENERIC DRUG PRODU					is this produc	or to be shipped	a to customers c	or ary icc:	No	
I. Orange Book Rating:	AB	Cian and the Ta	II. Brand Name:	Zocor									
III. Generic Equivalent fo			blets, 10 mg, 1000ct					c. Special regu	•			No	
	DRI	UG SUPPLY CHA	AIN SECURITY ACT (DSC	SA) INFORMATI	ION			Special return	ns requirement	s for this produc	ct?	No	
Does supplier meet DSC	SA definition of manu	ufacturer?	Yes	DUNS:	156861945								
Is product exempt from I	DSCSA?	No						d. Store produ	uct (unit of sal	e) upright?		Yes	
If yes, select exemption	on:		_					Protect pro	duct (unit of s	ale) from light?	?	No	
Other exemption - Wri									`	, ,			
Is product repackaged?		No	I/ W					. 01 -14 114	0.4				
		INU	it yes, was origina	ai product purci	hased direct from m	ifr?		e. Shelf life:	24	Months			
Is product sold by manu	facturer's exclusive d		if Yes, was originate No	ai product purci	hased direct from m	nfr?		e. Shelf life:		ife at launch (if	different):		Months
		listributor?			documentation from			e. Shelf life:			different):		Months
Is product sold by manu		listributor? de?	No	If yes, attach				e. Shelf life:	Initial shelf li		,		Months
Is product sold by manu		listributor? de?	No No	If yes, attach	documentation fron				Initial shelf li	fe at launch (if	ORMATION	Volume	
Is product sold by manu Are any waivers granted	for product ID/barco	listributor? de?	No No	If yes, attach ORDER INFOR What is the N	documentation fron			Weight Lbs.	Initial shelf li	fe at launch (if	ORMATION	Volume (Cube)	Months # Pieces:
Is product sold by manu Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barco	de? ADDITIONAL No No	No No No PRODUCT INFORMATION Unit of Sale X Bottle	If yes, attach	documentation from		Item:	Weight Lbs.	Initial shelf li	PACKING INF PACKING INF nensions (US m Height	ORMATION ismts.) Width:	(Cube)	
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MAT	RIAL HAZARD CLASSIFICATION and TRANSPORTATION
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?	Hazardous Waste Identification EPA Hazardous Waste Code:
(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)	(if yes, answer a-d below and provide SDS) a. DOT Hazard Class b. UN/ID Number c. Packing Group d. Inhalation Hazard?
Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization
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#	Level How? GTIN-14
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)
Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer	
Aerosol Class; Identify NFPA Storage Level:	RETURN INSTRUCTIONS
7 to loss of oldest, identify it if it is clouded between	Contact tel. # if product received damaged: 877-993-8779
	Is product returnable for credit:
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy: www.zydususa.com
Ephedrine	Special regulations or returns requirements for this product in certain states? No
Pseudoephedrine	If so, which states? Other requirements? Comments?
Phenylpropanolamine	
lodine (≥2.2%)	
Other:	
CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	If Unit Dose NDC, indicate NDC here:
Restricted to retail pharmacy only: No	MISCELLANEOUS NOTES and/or Image of Product Barcode:
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 d. Phone only Fax Number: Fax Number: Fax Number: Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
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: Comments:	Days of week overnight is available: Monday 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 #:
Comments.	Overnight Fees apply: Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
DEA #: PCPDP #: NPI #:	
Comments:	ADDITIONAL INFORMATION
Registry:	
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	