



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	090-174
Rx Product/Proprietary Name:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 30 ct
NDC:	68382-036-06
UPC:	368382036063
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '0' hard gelatin capsules with dark orange colored cap printed with "ZA-37" in black ink & white body printed with "150 mg" in black ink.
Active ingredients:	Venlafaxine
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) _____
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	_____
Number:	_____
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 30 ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	156861945
Is product exempt from DSCSA?	No
If yes, select exemption:	_____
Other exemption - Write in:	_____
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	_____
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	_____

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	_____
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.?	_____
(incl. N for non-narcotic)	
Controlled Substance Code:	_____
Hazardous Material/Cytotoxic Agent?	No
Is Item... _____	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	_____
Is it reverse numbered?	_____

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	32.48 G		3.025	1.614	4.88235	
Box/ Carton:					0	
Case:	3.20LBS	7.76	4.06	11.54	363.574624	24
Pallet:		47.24	50.39	39.37	93717.2771	144
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer? <input type="checkbox"/>	_____	Size/Strength/Form:	30ct/150mg/Capsules
(Write-in, e.g. 1 Vial)		Product Shape:	Capsules
Rx billing unit to pharmacy:		Product Color:	Dark orange/White
<input checked="" type="checkbox"/> Each		Product Imprint:	ZA37 150mg
<input type="checkbox"/> Gram			
<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$14.95	
As of date: <input type="text" value="9/10/2014"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: _____



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

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

Carcinogen
 Reproductive Toxicant
 Both
 Warning appears on label

c. Contact Hazard? No

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

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
 RQ Threshold:

Is this a marine pollutant? No

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

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

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger
 Cargo
 Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization							
Serialized?	Yes	Level	How?	RFID	GTIN-14		
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	RFID	10368382036060
If not, when?	<input type="text"/>	Box/ Carton	2D	Linear	<input type="checkbox"/>	RFID	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	RFID	
		Pallet	2D	Linear	<input type="checkbox"/>	RFID	

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic
 Antineoplastic Steroid/Androgen
 Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

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

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

Ephedrine
 Pseudoephedrine
 Phenylpropanolamine
 Iodine (≥2.2%)
 Other:

RETURN INSTRUCTIONS

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

Is product returnable for credit:

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

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

If so, which states? Other requirements? Comments?

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments) No

Comments:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Rx Product Only)

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PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	090-174
Rx Product/Proprietary Name:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 90 ct
NDC:	68382-036-16
UPC:	368382036162
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '0' hard gelatin capsules with dark orange colored cap printed with "ZA-37" in black ink & white body printed with "150 mg" in black ink.
Active ingredients:	Venlafaxine
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 90 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	68.42 G		3.97	2.21	8.7737	
Box/ Carton:					0	
Case:	5.35LBS	10.12	5	15.08	763.048	24
Pallet:		47.24	47.83	39.37	88956.0898	63
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer? <input type="checkbox"/>	Size/Strength/Form:
<input type="text"/>	90ct/150mg/Capsules
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsule
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	Dark orange/White
	Product Imprint:
	ZA37 150mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$44.85	
As of date: <input type="text" value="9/10/2014"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

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

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
RQ Threshold:

Is this a marine pollutant? No

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

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

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

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	10368382036169
If not, when?	<input type="text"/>	Box/Carton	2D	Linear	<input type="checkbox"/>	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	
		Pallet	2D	Linear	<input type="checkbox"/>	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

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

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

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

Is product returnable for credit:

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

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

If so, which states? Other requirements? Comments?

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

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments) No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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

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



Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	090-174
Rx Product/Proprietary Name:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 1000 ct
NDC:	68382-036-10
UPC:	368382036100
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '0' hard gelatin capsules with dark orange colored cap printed with "ZA-37" in black ink & white body printed with "150 mg" in black ink.
Active ingredients:	Venlafaxine
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	
	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 150 mg, 1000 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	<input type="text" value="No"/> No
State Control?	<input type="text" value="No"/> No
ARCOS reportable?	<input type="text" value="No"/> No
Co-Licensed?	<input type="text" value="No"/> No
Controlled Substance?	<input type="text" value="No"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	552.10 G		7.35	4.91	36.0885	
Box/ Carton:					0	
Case:	18.60LBS	15.94	8.84	21.22	2990.10171	12
Pallet:		47.24	45.28	39.37	84213.5009	16
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer? <input type="text"/>	Size/Strength/Form: <input type="text" value="1000ct/150mg/Capsules"/>
(Write-in, e.g. 1 Vial)	Product Shape: <input type="text" value="Capsule"/>
Rx billing unit to pharmacy:	Product Color: <input type="text" value="Dark orange/White"/>
<input checked="" type="checkbox"/> Each	Product Imprint: <input type="text" value="ZA37 150mg"/>
<input type="checkbox"/> Gram	
<input type="checkbox"/> Milliliter	

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$395.30	
As of date: <input type="text" value="9/10/2014"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

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

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
RQ Threshold:

Is this a marine pollutant? No

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

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

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

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

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

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments) No

Comments:

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level		How?		RFID		GTIN-14
		Item	2D	Linear	Linear	RFID	RFID	10368382036107
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Items aggregated to case?	<input type="text"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

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

RETURN INSTRUCTIONS

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

Is product returnable for credit:

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

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

If so, which states? Other requirements? Comments?

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

