



# 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, 37.5 mg, 30 ct
NDC:	68382-034-06
UPC:	368382034069
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '3' hard gelatin capsules with grey colored cap printed with "ZA-35" in black ink & white body printed with "37.5 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*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 37.5 mg, 30 ct

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

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

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Powder Multi
	<input type="checkbox"/> Other: Write In
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:	22.37 G		3.025	1.615	4.88538	
Box/ Carton:					0	
Case:	2.65LBS	7.76	4.06	11.54	363.574624	24
Pallet:		47.24	50.39	39.37	93717.2771	144
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?	Size/Strength/Form:
<input type="text"/>	30ct/37.5mg/Capsules
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsules
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Grey/White
<input type="checkbox"/> Milliliter	Product Imprint:
	ZA35 37.5mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$12.25	
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"/>	10368382034066
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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="checkbox"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="checkbox"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
REMS or Registry Restrictions	Return Instructions
<p><b>REMS:</b> <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><input type="text"/></p>
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	



# Standard Pharmaceutical Product Information (Rx Product Only)

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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, 37.5 mg, 90 ct
NDC:	68382-034-16
UPC:	368382034168
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '3' hard gelatin capsules with grey colored cap printed with "ZA-35" in black ink & white body printed with "37.5 mg" in black ink.
Active ingredients:	Venlafaxine
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 37.5 mg, 90 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Legend Device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
State Control?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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?	<input type="text" value="1"/> Yes
If Yes, how many of which package type?	
	<input type="text"/> Each
	<input type="text"/> Inner/Carton/Pack
	<input type="text"/> Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	32.10 G		3.425	1.878	6.43215	
Box/ Carton:					0	
Case:	3.45LBS	8.7	4.45	12.95	501.35925	24
Pallet:		47.24	48.03	39.37	89328.0576	104
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/37.5mg/Capsules
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsules
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	Grey/White
	Product Imprint:
	ZA35 37.5mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$36.75	
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"/>	10368382034165
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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>
REMS or Registry Restrictions	ADDITIONAL INFORMATION
<p><b>REMS:</b> <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 20px;" type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 20px;" type="text"/></p>	<p style="text-align: center; background-color: #0056b3; color: white; padding: 2px;"><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p style="width: 100%; height: 100px;"><input style="width: 100%; height: 100%;" type="text"/></p>



# 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, 37.5 mg, 1000 ct
NDC:	68382-034-10
UPC:	368382034106
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '3' hard gelatin capsules with grey colored cap printed with "ZA-35" in black ink & white body printed with "37.5 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*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	Initial shelf life at launch (if different): <input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor XR
III. Generic Equivalent for Brand:	Venlafaxine HCL Extended-Release Capsules, 37.5 mg, 1000 ct

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	167.76 G		6.41	3.52	22.5632	
Box/ Carton:					0	
Case:	8.25LBS	11.69	7.44	15.55	1352.43948	12
Pallet:		47.24	47.64	39.37	88602.7204	45
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer? <input type="checkbox"/>	<input type="text"/>	Size/Strength/Form:	1000ct/37.5mg/Capsules
	(Write-in, e.g. 1 Vial)	Product Shape:	Capsules
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	Grey/White
	<input type="checkbox"/> Gram	Product Imprint:	ZA35 37.5mg
	<input type="checkbox"/> Milliliter		

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$323.82	
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"/>	10368382034103
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:



