



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	90739
Rx Product/Proprietary Name:	Duloxetine Delayed Release Capsules, 20mg 60s
NDC:	68382-385-14
UPC:	368382385147
CVX Code:	
MVX Code:	
Description:	white to off-white free flowing pellets filled in size '4' hard gelatin capsules with green colored cap printed with "241" in golden ink and white body printed with "20 mg" in golden ink
Active ingredients:	Duloxetine Hydrochloride
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Cymbalta
III. Generic Equivalent for Brand:	Duloxetine Delayed Release Capsules, 20mg 60s

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

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	What is the NDC selling unit? <input type="text" value="Each"/>
Legend Device?	<input type="text" value="No"/>	<input checked="" type="checkbox"/> Bottle	
State Control?	<input type="text" value="No"/>	<input type="checkbox"/> Box/Carton	
ARCOS reportable?	<input type="text" value="No"/>	<input type="checkbox"/> Ampule	
Co-Licensed?	<input type="text" value="No"/>	<input type="checkbox"/> Glass	
Controlled Substance?	<input type="text" value="No"/>	<input type="checkbox"/> Tube	
Schedule No.?	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Powder Sgl	
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>	<input type="checkbox"/> Vial Power Multi	
Is Item...	<input type="text"/>	<input type="checkbox"/> Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Minimum order quantity? <input type="text" value="Yes"/>	
Is it reverse numbered?	<input type="text"/>	If Yes, how many of which package type?	
		<input type="text"/>	Each
		<input type="text" value="1"/>	Inner/Carton/Pack
			Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	38.41g		2.982	1.609	4.798038	60
Box/ Carton:					0	
Case:	3.204	6.7	4.02	10.1	272.0334	24
Pallet:		47	39	47	86151	160
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT	Other Product Information
Vendor #:	<input type="text"/>	Rec. sell unit to customer? <input type="text"/>	Size/Strength/Form: <input type="text" value="60/20mg/Capsule"/>
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	Product Shape: <input type="text" value="Capsule"/>
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Color: <input type="text" value="Green/White"/>
		<input checked="" type="checkbox"/> Each	Product Imprint: <input type="text" value="241 20mg"/>
		<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
	\$251.94	
As of date: <input type="text" value="4/28/2015"/>		

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: