



# 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 (drug); PMA/510(k)(med device):	207743
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	LABETALOL TABLETS USP, 200MG
Selling Unit NDC:	6838279901
Individual Unit NDC:	
UPC:	368382799012
UDI	
CVX Code:	
MVX Code:	
Description:	white to off white colored, round, biconvex, film-coated tablets debossed with "7" and "99" on either side of score line on one side and plain on other side.
Active Ingredient(s):	LABETALOL
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
State:	NJ
Address 2:	
Zip:	08534
Email:	
Fax:	(609) 730 1998

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	
Name:	
Number:	
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only?	<input type="checkbox"/> No
Is the Product... Neither?	<input type="checkbox"/> No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	100 COUNT
Strength:	200MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	WHITE TO OFF-WHITE
Product Imprint:	"7" "99"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 TABLETS
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? <input type="checkbox"/> Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/Carton/Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	LABETALOL
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 BOTTLE OF 100 TABLETS"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.1	1.61	2.87	1	4.6207	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	3.22	9.72	3.94	6.5	248.9292	24
Pallet:	654	48	40	48	92160	4752
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
If not, when?						
Items aggregated?						
<input type="checkbox"/> No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382799012		
3/1/2018	<input type="checkbox"/> Box/Case/Bundle/Inner Pack	<input type="checkbox"/>				
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	24	40368382799010		
	<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/>		80368382799018		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			



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Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

DUNS:

Proprietary Name (If Applicable) and Established Name:

Selling Unit NDC:  Individual Unit NDC:  UPC:

UDI  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:  Address 2:

City:  State:  Zip:

Key Contact:  Email:

Phone Number:  Fax:

Product Therapeutic Classification:

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:   
 Other Temperature Range Requirement (write in):

Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:  
 Name:   
 Number:   
 Group E-mail:

c. Special regulations for product in any states?  
 Special returns requirements for this product?

d. Store product (unit of sale) upright?   
 Protect product (unit of sale) from light?

e. Shelf life:  
 Initial shelf life at launch (if different):  Months

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product... Direct-Ship Only   
 Is the Product... Neither

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose NDC, indicate NDC here:

Country of Origin:

Is this product covered under the Trade Agreements Act (TAA)?

**PRODUCT DESCRIPTION INFORMATION**

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

**ORDER INFORMATION**

Unit of Sale  
 Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 Other: Write In

What is the NDC selling unit?  
  
 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?  
 Each  
 Inner/Carton/Pack  
 Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?   
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  GLN:

Is product exempt from DSCSA?   
 If yes, select exemption:  
 Other exemption - Write in:

Is product repackaged?  If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor?  If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.		Dimensions (US msmts.)			Volume (Cube)	# Pieces:
			Depth	Height	Width		
Item:	0.41		2.64	4.97	2.64	34.638912	1
Box/Carton/Bundle/Inner Pack:						0	
Case:	6.04		10.74	5.98	8.11	520.866372	12
Pallet:	597		48	40	48	92160	1152
UPC:							
Case:							
Carton:							

**GTIN PRODUCT INFORMATION**

Serialized?	No	Level	Saleable Unit	Quantity	GTIN-14
If not, when?	<input type="text" value="3/1/2018"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="text" value="1"/>	<input type="text" value="00368382799050"/>
Items aggregated?	<input type="text" value="Yes"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="text" value="12"/>	<input type="text" value="40368382799058"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text" value="80368382799056"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>

**COST INFORMATION**

Regular Cost:   
 Invoice Cost (WAC) (\$):   
 Federal Excise Tax Per Unit of Sale:   
 As of date:

**WHOLESALE USE ONLY:**  
 Vendor #:   
 Whsl. Code #:   
 Finline Code: