



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	201676
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	Sirolimus Tablets, 0.5 mg 100's
Selling Unit NDC:	68382-520-01
Individual Unit NDC:	
UPC:	368382520012
UDI	
CVX Code:	
MVX Code:	
Description:	"yellow, round, biconvex, coated tablets imprinted with "1" in black ink on one side
Active Ingredient(s):	Sirolimus
URL for Additional Product Information:	www.zydususa.com
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77°)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
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?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
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:	100 COUNT
Strength:	0.5 mg
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	YELLOW
Product Imprint:	1

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Rapamune
<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:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	36.00 G	1.615	3.025	1.615	7.88988063	
Box/Cartron/Bundle/Inner Pack:					0	
Case:	3.66 LBS	6.73	4.02	10.08	272.710368	24
Pallet:	666	47.24	48	39.37	89272.2624	3840
UPC:	Case:					
	Cartron:					

GTIN PRODUCT INFORMATION						
Serialized?	No	Level	Saleable Unit	Quantity	GTIN-14	
If not, when?	1/1/2018	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382520012	
Items aggregated?	Yes	<input checked="" type="checkbox"/> Box/Cartron/Bundle/Inner Pack	<input type="checkbox"/>			
		<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40368382520010	
		<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382520018	
			<input type="checkbox"/>			
			<input type="checkbox"/>			
			<input type="checkbox"/>			
			<input type="checkbox"/>			
			<input type="checkbox"/>			
			<input type="checkbox"/>			
			<input type="checkbox"/>			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$682.43	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	7/14/2017		