



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Strides Pharma Inc."/>
Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="79128"/>
Rx Product/Proprietary Name:	<input type="text" value="Lamivudine and Zidovudine Tablets USP 150 / 300mg"/>
NDC:	<input type="text" value="64380-707-03"/>
UPC:	<input type="text" value="364380707035"/>
CVX Code:	<input type="text"/>
MX Code:	<input type="text"/>
Description:	<input type="text" value="White colored oval shaped film coated tablet with 'LZ' engraved on one side and break line on other side."/>
Active ingredients:	<input type="text" value="Lamivudine and Zidovudine"/>
URL for Additional Product Information:	<input type="text"/>
Address:	<input type="text" value="201 South Main Street, Ste 3"/>
Address 2:	<input type="text"/>
City:	<input type="text" value="Lambertville, NJ 08530"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="8530"/>
Key Contact:	<input type="text" value="J B Davis"/>
Email:	<input type="text" value="sales@stridesusa.com"/>
Phone Number:	<input type="text" value="(855) 273-0146"/>
Fax:	<input type="text" value="(855) 228-9481"/>

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" value="Nagesh Majeti"/>
Number:	<input type="text" value="609-773-5004"/>
Is this product to be shipped to customers on ice?	<input type="checkbox"/>
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="checkbox"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/>
e. Shelf life:	
<input type="text" value="24"/> Months	<input type="text"/>
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Brand Name:	<input type="text" value="Combivir Tablets"/>
III. Generic Equivalent for Brand:	<input type="text" value="Lamivudine and Zidovudine Tablets"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="No"/>
DUNS:	<input type="text"/>
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="checkbox"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="Yes"/>
Are any waivers granted for product ID/barcode?	<input type="checkbox"/>
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Legend Device?	<input type="text" value="No"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
State Control?	<input type="text" value="No"/>	What is the NDC selling unit?	<input type="text" value="1 Container of 60 Tablets"/>
ARCOS reportable?	<input type="text" value="No"/>	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Co-Licensed?	<input type="text" value="No"/>	Minimum order quantity?	<input type="text"/>
Controlled Substance?	<input type="text" value="No"/>	If Yes, how many of which package type?	<input type="text"/>
Schedule No.?	<input type="text"/>	<input type="checkbox"/> Each	<input type="checkbox"/> Inner/Carton/Pack
(incl. N for non-narcotic)		<input type="checkbox"/> Case	
Controlled Substance Code:	<input type="text"/>		
Hazardous Material/Cytotoxic Agent?	<input type="text"/>		
Is Item... <input type="text"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
Is it reverse numbered?	<input type="checkbox"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.157	1.654	3.543	1.654	9.69264179	1
Box/ Carton:	N/A	N/A	N/A	N/A	N/A	N/A
Case:	4.514	11.614	5.512	7.953	509.122175	24
Pallet:	509.122	47.992	38.307	40	73537.1818	108
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" value="1 container"/>	Size/Strength/Form:	<input type="text" value="60's 150 mg / 300mg"/>
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	<input type="text" value="Oval"/>
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	<input type="text" value="White"/>
		<input type="checkbox"/> Gram		Product Imprint:	<input type="text" value="LZ' on one side and break line on other"/>
		<input type="checkbox"/> Milliliter			

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

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: