Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type: New Item | [ ] Final Version | **Date:** 4/27/2018

PRODUCT INFORMATION

Company Name: ZYDUS PHARMACEUTICALS (USA) INC. | **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 209467
DUNS: 156861945
Proprietary Name (If Applicable) and Established Name: SUCCINYLCHOLINE CHLORIDE INJECTION USP, 200MG/10mL
Selling Unit NDC: 70710-1377-2 | **Individual Unit NDC:** | **UPC:** 370710137724
UDI | **CVX Code:** | **MVX Code:**
Description: clear, colorless solution
Active Ingredient(s): SUCCINYLCHOLINE CHLORIDE
URL for Additional Product Information:
Address: 73 ROUTE 31 NORTH | **Address 2:**
City: PENNINGTON | **State:** NJ | **Zip:** 08534
Key Contact: | **Email:**
Phone Number: (609) 730 1900 | **Fax:** (609) 730 1998
Product Therapeutic Classification:

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:	1 X 25 MD VIALS
Strength:	200MG/10mL
Dosage Form:	VIAL
Product Shape:	NA
Product Color:	
Product Imprint:	NA

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP
II. Generic Equivalent to What Brand?: QUELICIN

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.

GTIN PRODUCT INFORMATION

Serialized? No
If not, when? 7/1/2018
Items aggregated? Yes

Level		Saleable Unit	2D	Linear	Quantity	GTIN-14
	Item		2D	Linear		
X	Box/Carton/Bundle/Inner Pack	X	X 2D	Linear	1	00370710137724
X	Case		X 2D	Linear	12	40370710137722
X	Pallet		X 2D	Linear	720	80370710137720
			2D	Linear		
			2D	Linear		
			2D	Linear		
			2D	Linear		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Cold – between 2 and 8 C (36° – 46° F)
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? No
Special returns requirements for this product?

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? No

e. Shelf life: 18 **Months**
Initial shelf life at launch (if different): **Months**

ORDER INFORMATION

Unit of Sale

	Bottle
X	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
X	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit?
1 BOX OF 25 VIALS
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
X	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

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

Rx billing unit to pharmacy:

X	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:		0.94	1.77	0.94	1.563972	1
Box/Carton/Bundle/ Inner Pack:	0.05	5.19	2.36	5.19	63.569196	25
Case:	17.29	10.71	10.71	7.68	880.927488	12
Pallet:	1055	48	40	48	92160	720
UPC:	**Case:**					
	Carton:					

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$479.50
Federal Excise Tax Per Unit of Sale	
As of date:	7/18/2018

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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: