

Date:11/16/2020 15:00:58

Created Date Created by

2020-02-04 12:28:16.0 dem1330

Registration Expiration Date Registration Renewed Date

2022-12-31 2020-11-16

Last Updated Registration Status Reason

2020-11-16 Initial registration

Registration Status

VALID

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?

•Yes ONo

Section 1: Type of Registration

Facility Location: Domestic Registration

UPDATE OF REGISTRATION INFORMATION:

Registration Number: 17067591328 Pin No 6xeEhh46

Are you the new owner of a previously registered facility?

Oyes ONo

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

Section 2: Facility Name/Address Information

Facility Name Telephone Number

COVEX USA INC 001 305 6700979

Facility Name Suffix Fax Number

Corporation 001 954 2066880

Facility Street Address, Line 1 E-Mail Address

8950 Sw 74th Ct Ste 1406 covex_usa@covex.com

Facility Street Address, Line 2 Unique Facility Identifier (UFI)

117122995

City

Miami

State/Province/Territory

Florida

Zip Code (Postal Code)

33156

Country/Area

UNITED STATES



Country/Area SINGAPORE

Section 3: Preferred Mailing Address In	formation	
Complete this section if different from Section 2 Facil	ity Name/Address Information (OPTIONAL)	
Is the preferred mailing address the same as the faci	lity address (Section 2)? Yes	
Name	Telephone Number	
COVEX USA INC	001 305 6700979	
Address, Line 1	Fax Number	
8950 Sw 74th Ct Ste 1406	001 954 2066880	
Address, Line 2	E-Mail Address	
	covex_usa@covex.com	
City		
Miami		
State/Province/Territory		
Florida		
Zip Code (Postal Code)		
33156		
Country/Area		
UNITED STATES		
Section 4: Parent Company Name/Addre	ess Information	
(If applicable and if different from Sections 2 and 3).	If information is the same as another section, check which section:	9
OSame as Facility Address (Section 2)		
OSame as Preferred Mailing Address (Section 3)		

Zip oode (i ostal oode)	
33156	
Country/Area	
UNITED STATES	
Section 4: Parent Company Name/Address In	nformation
(If applicable and if different from Sections 2 and 3). If inform	mation is the same as another section, check which section:
OSame as Facility Address (Section 2)	
OSame as Preferred Mailing Address (Section 3)	
None of the above	
Company Name	Telephone Number
Pioneer Pharma (Singapore) Pte. Ltd	065 981 16356
Company Name Suffix	Fax Number
Other	
Company Name Suffix Other	
LTD	
Address, Line 1	E-Mail Address
33A Chander Road	
Address, Line 2	
City	
Singapore	
State/Province/Territory	
Central Singapore	
Zip Code (Postal Code)	
219539	



Section 5: Facility Emergency Contact Information	tion								
If information is the same as another section, check which sec	ction:								
OSame as Facility Address (Section 2)									
⊙ None of the above									
Individual's Title (Optional)	Emergency Contact Phone								
Dr	001 305 6700979								
Individual's Name (Optional)	E-Mail Address								
Tania	tm@demosglobal.es Job Title (Optional)								
Individual's Middle Name (Optional)									
Individual's Last Name (Optional) Martinez	50° 50° 50°								
Section 6: Trade Names									
	on 2 above, list them below (e.g., "Also doing business as," "Facility also known as")) on to the name provided in Section 2: Facility Name/Address Information?								
OYes									
⊙No									
Section 7: United States Agent	.40 .40								
(To be completed by facilities located outside any state or terri	itory of the United States, District of Columbia, or The Commonwealth of Puerto Rico)								
First Name	Emergency Contact Phone								
-N/A-	-N/A-								
Middle Name (Optional)	Fax Number								
-N/A-	-N/A-								
Last Name (Optional)	E-Mail Address								
-N/A-	-N/A-								
Title (Optional)									
-N/A-									
Address, Line 1									
-N/A-									
Address, Line 2									
-N/A-									
City -N/A-									
State/Province/Territory -N/A-									
Zip Code (Postal Code) -N/A-									
Country/Area									



Section 8: Seasonal Facility Dates of Operation (Optional)

			·		<u> </u>								
Give the approxi	mate dates that y	our facility is open	n for business, if it	s operati	ons are	on a seas	sonal bas	sis (Optio	nal).				
Harvest 1													
Start Month				End Month									
Harvest 2													
Start Month			•		End Mo	nth							
Section 9: Ge	eneral Produc	ct Categories	- Human/Ani	mal/Bo	th								
☑ Food for Human Consumption					☐Food for Animal Consumption								
Section 9a: 6 Facility	∋eneral Produ	uct Categories	s - Food for H	luman	Consu	ımptioı	n; and	Туре о	of Activ	ity Coı	nducte	d at the	e
To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37	Storage Warehouse / Holding Facility (e.g., storage	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)		Low- Acid Food Process or	Interstat e Conveya nce Caterer / Catering Point	Contract	Labeler / Relabele	Manufact urer / Process or	Packer / Repacke r	Salvage Operator (Recondi tioner)	Farm Mixed- Type Facility	Other Activity Conduct ed (Please Specify)
11.DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods)(21 CFR 170.3 (n)													
Other Activity Condu	ıcted			<i>></i> C									
Importer													
Provide the follow section: If information is the operation of the analysis of the following section 2 - Far O Section 4 - Par O Section 7 - US O None of the analysis of the section of	wing information, the same as Secti acility Address Info referred Mailing A arent Company Ad S Agent Address	ddress Information	I other sections or ox: n	n the form	n. If infor			ne as and	other sect	ion of the	e form, cl	neck which	ch



Address, Line 1

8950 Sw 74th Ct Ste 1406

Address, Line 2

Miami

City

State/Province/Territory

Florida

Zip Code (Postal Code)

33156

Country/Area

UNITED STATES

Telephone Number

001 305 6700979

Fax Number

001 954 2066880

E-Mail Address

covex_usa@covex.com

Section 11: Inspection Statement

☑FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12: Certification Statement

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

NAME OF PERSON SUBMITTING THIS REGISTRATION RENEWAL: Shirley Mazza

CHECK ONE BOX

Oa. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)

OB. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

Individual's Name

Address, Line 1

-N/A-

Address, Line 2

-N/A-

City

-N/A-

-N/A-

State/Province/Territory

-N/A-

Zip Code (Postal Code)

-N/A-

Telephone Number

-N/A-

Fax Number

-N/A-

E-Mail Address

-N/A-



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