



Date:10/24/2024 20:32:49

Created Date

2024-10-15 00:05:13.0

Registration Expiration Date

2026-12-31

Last Updated

2024-10-24

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 ☐ No

Are you a fishing vessel engaged in processing (21 CFR 1.226(f))?

☐ Yes ☒ No

Section 1: Type of Registration

Facility Location: Foreign Registration

UPDATE OF REGISTRATION INFORMATION:

Registration Number: 16672711182 Pin No 4cj4xF49

Are you the new owner of a previously registered facility?

☐ Yes ☒ No

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

Section 2: Facility Name/Address Information

Facility Name

Xinkailian Biotechnology (Hainan) Co., Ltd

Facility Name Suffix

Limited

Facility Street Address, Line 1

M-6, Building-1, No.8, Yaogu Erheng Road, Xiuying District

Facility Street Address, Line 2

City

Haikou

State/Province/Territory

Hainan

Zip Code (Postal Code)

570311

Country/Area

CHINA

Telephone Number

086 177 86900805

Fax Number

E-Mail Address

60@zuoce.org

Unique Facility Identifier (UFI)



Section 3: Preferred Mailing Address Information

Complete this section if different from Section 2 Facility Name/Address Information (OPTIONAL)

Is the preferred mailing address the same as the facility address (Section 2)? Yes

Name Telephone Number

Xinkailian Biotechnology (Hainan) Co., Ltd **086 177 86900805**

Address, Line 1 Fax Number

M-6, Building-1, No.8, Yaogu Erheng Road, Xiuying District

Address, Line 2 E-Mail Address

60@zuoce.org

City

Haikou

State/Province/Territory

Hainan

Zip Code (Postal Code)

570311

Country/Area

CHINA

Section 4: Parent Company Name/Address Information

(If applicable and if different from Sections 2 and 3). If information is the same as another section, check which section:

☒ Same as Facility Address (Section 2)

☐ Same as Preferred Mailing Address (Section 3)

☐ None of the above

Company Name Telephone Number

Xinkailian Biotechnology (Hainan) Co., Ltd **086 177 86900805**

Company Name Suffix Fax Number

Limited

Address, Line 1 E-Mail Address

M-6, Building-1, No.8, Yaogu Erheng Road, Xiuying District **60@zuoce.org**

Address, Line 2

City

Haikou

State/Province/Territory

Hainan

Zip Code (Postal Code)

570311

Country/Area

CHINA

Section 5: Facility Emergency Contact Information



If information is the same as another section, check which section:

- ☒ Same as Facility Address (Section 2)
- ☐ Same as U.S. Agent Information (Section 7)
- ☐ None of the above

Individual's Title (Optional)

Emergency Contact Phone

086 177 86900805

Individual's Name (Optional)

E-Mail Address

60@zuoce.org

Individual's Middle Name (Optional)

Job Title (Optional)

Individual's Last Name (Optional)

Section 6: Trade Names

(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))

Are there alternate trade names used by your facility in addition to the name provided in **Section 2: Facility Name/Address Information?**

- ☐ Yes
- ☒ No

Section 7: United States Agent

(To be completed by facilities located outside any state or territory of the United States, District of Columbia, or The Commonwealth of Puerto Rico)

First Name

Telephone Number

Wei

713 5053208 null

Middle Name (Optional)

Emergency Contact Phone

713 5053208

Last Name

Fax Number

Huang

Title (Optional)

E-Mail Address

Mr.

xuhfr@163.com

Address, Line 1

3303 Belmont river In

Address, Line 2

City

Katy

State/Province/Territory

Texas

Zip Code (Postal Code)

77494

Country/Area

UNITED STATES

Section 8: Seasonal Facility Dates of Operation (Optional)

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis (Optional).



Harvest 1

Start Month

End Month

Harvest 2

Start Month

End Month

Section 9: General Product Categories - Human/Animal/Both

☒ Food for Human Consumption

☐ Food for Animal Consumption

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Process or	Low-Acid Food Process or	Interstate Conveyance Caterer / Catering Point	Contract Sterilizer	Labeler / Relabeler	Manufacturer / Processor	Packer / Repacker	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity Conducted (Please Specify)
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12. DIETARY SUPPLEMENT CATEGORIES

a. Proteins, Amino Acids, Fats and Lipid Substances ^[21 CFR 170.3(o) (20)]	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐
b. Vitamins and Minerals	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐
c. Animal By-Products and Extracts	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐
d. Herbals and Botanicals	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐

Section 10: Owner, Operator, or Agent-in-Charge Information

Provide the following information, if different from all other sections on the form. If information is the same as another section of the form, check which section:

If information is the same as Section 2, check the box:

- ☒ Section 2 - Facility Address Information
- ☐ Section 3 - Preferred Mailing Address Information
- ☐ Section 4 - Parent Company Address Information
- ☐ Section 7 - US Agent Address Information
- ☐ None of the above

Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge: Xiaojing Guo



Address, Line 1

M-6, Building-1, No.8, Yaogu Erheng Road, Xiuying District

Address, Line 2

City

Haikou

State/Province/Territory

Hainan

Zip Code (Postal Code)

570311

Country/Area

CHINA

Telephone Number

086 177 86900805

Fax Number

E-Mail Address

60@zuoce.org

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 FORM: Wallace Xu

CHECK ONE BOX

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

☐ B. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

Individual's Name

-N/A-

Telephone Number

-N/A-

Address, Line 1

-N/A-

Fax Number

-N/A-

Address, Line 2

-N/A-

E-Mail Address

-N/A-

City

-N/A-

State/Province/Territory

-N/A-

Zip Code (Postal Code)

-N/A-



Country/Area

-N/A-