

## FACTORY PROFILE

Please provide the following information by email to: [USFDAForeignFoodInspectionPlanning@fda.hhs.gov](mailto:USFDAForeignFoodInspectionPlanning@fda.hhs.gov) to assist the U.S.FDA in planning and scheduling an inspection at your Facility.

### Facility Information

1. Facility Name:	
2. Address of the Main Office or Headquarters (if different than the manufacturing address):	
3. Manufacturing Address (English) include City, State/Province/Area, Country, Country Code or Zip Code Physical Address: _____ Mailing Address (if different): _____	
4. Manufacturing Address (Native/Local Language) include City, State/Province/Area, Country, Country Code or Zip Code:	
5. Using <a href="https://www.mapcoordinates.net/en">https://www.mapcoordinates.net/en</a> , what is your Firms Manufacturing location: Latitude: _____ Longitude: _____	
6. Does the Firm conduct business under any other name? <input type="checkbox"/> Yes (Please List) <input type="checkbox"/> No	
7. Is the Firm associated with a parent company, holding company, group organization, or have a subsidiary or affiliate firms? <input type="checkbox"/> Yes (Please List) <input type="checkbox"/> No	
8. Does the Firm, including all associated companies and subsidiaries, average over \$10,000,000 in annual sales for each of the previous 3 years? <input type="checkbox"/> Yes <input type="checkbox"/> No	
9. Does the Firm have additional manufacturing locations (i.e. farm or additional packing site)? <input type="checkbox"/> Yes (Please List, and submit a separate Factory Profile for each location) <input type="checkbox"/> No	
10. The manufacturing location is near what major city?	
11. Facility Contact Information: i. Telephone number (include country code): _____ ii. Email Address: _____ iii. Website(s): _____	
12. What are the DAYS and HOURS of production? (Example: M - F 0800 - 1700)	
13. Is your facility in production the entire year? <input type="checkbox"/> Yes <input type="checkbox"/> No i. If "No", when is the growing season or seasonality? Specify months of peak operation:	

ii. Please describe any issues that may impact scheduling of this inspection (Holidays/Planned Shutdowns):

14. Number of full time employees:

15. Number of seasonal employees:

16. Facility Size (Example: 200 m<sup>2</sup>):

17. What types of activities are conducted at your Facility? (Check all that apply)

- |                                          |                                               |                                            |                                                 |
|------------------------------------------|-----------------------------------------------|--------------------------------------------|-------------------------------------------------|
| <input type="checkbox"/> Ambient Storage | <input type="checkbox"/> Refrigerated Storage | <input type="checkbox"/> Frozen Storage    | <input type="checkbox"/> Manufacturer/Processor |
| <input type="checkbox"/> Warehouse       | <input type="checkbox"/> Packer/Repacker      | <input type="checkbox"/> Labeler/Relabeler | <input type="checkbox"/> Farm                   |
| <input type="checkbox"/> Other:          |                                               |                                            |                                                 |

18. Manufactured products/commodities: (Check all that apply)

- |                                              |                                       |                                              |                                                      |
|----------------------------------------------|---------------------------------------|----------------------------------------------|------------------------------------------------------|
| <input type="checkbox"/> Cheese              | <input type="checkbox"/> Grower/Farm  | <input type="checkbox"/> Acidified Food (AF) | <input type="checkbox"/> Low Acid Canned Food (LACF) |
| <input type="checkbox"/> Seafood/HACCP       | <input type="checkbox"/> Juice/HACCP  | <input type="checkbox"/> Infant Formula      | <input type="checkbox"/> Infant Formula Ingredient   |
| <input type="checkbox"/> Dietary Supplements | <input type="checkbox"/> Medical Food | <input type="checkbox"/> Animal Food         |                                                      |
| <input type="checkbox"/> Other:              |                                       |                                              |                                                      |

### Low Acid Canned Food (LACF) / Acidified Food (AF)

19. Please provide your Food Canning Establishment (FCE) number if you manufacture LACF or AF products:

**LACF** products are any food (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85 (excluding tomatoes and tomato products having a finished equilibrium pH less than 4.7) placed into a hermetically sealed container that can include cans, bottles, pouches, etc.

**AF** products are any low-acid food (pH > 4.6) to which acid(s) or acid food(s) are added and which has a finished equilibrium pH of 4.6 or below and a water activity (aw) greater than 0.85 that are placed into hermetically sealed container that can include cans, bottles, pouches, etc.

**Exclusions from LACF/AF:** Carbonated beverages, jams/jellies, acid foods, fermented foods, and refrigerated/frozen products. However, carbonated beverages, acid foods, and jams or jellies containing small amounts of low acid ingredients ( $\leq 10\%$ ) that cause a significant shift in the finished pH from that of the predominate acid food or acid are considered acidified foods; if the low acid ingredient(s) are  $>10\%$  then it is an acidified food. Fermented foods with low acid ingredients added are also considered acidified foods.

If you manufacture LACF or AF products that are exported to the United States, you must have a Food Canning Establishment Registration and a Process Filling for each product, product style, container size/type and processing method. For questions contact the LACF Team by email [LACF@FDA.HHS.GOV](mailto:LACF@FDA.HHS.GOV) or you can file online electronically at <https://www.access.fda.gov/>.

### Dietary Supplements

20. Do you manufacture a dietary supplement or dietary supplement ingredients?

- Yes  No

If "YES", answer the following questions:

i. Do any of the dietary supplements or dietary supplement ingredients that you manufacture consist of more than one ingredient?

- Yes  No

ii. If you manufacture a single ingredient, is it sold to the consumer without further processing?

- Yes  No  Not Applicable

iii. Do you send a single or blended ingredient to another firm for further processing or manipulation?

- Yes  No

Explain:

iv. Do you package, label, or distribute a dietary supplement manufactured by another firm?

- Yes  No



v. Do you manufacture a dietary supplement that is packaged or labeled by another firm?

- Yes                       No

vi. Is the name of your firm on the label of any product being shipped to the United States?

- Yes                       No

vii. Do you sell your products directly to consumers?

- Yes                       No

viii. Is your dietary supplement manufactured/produced for:

- Human consumption       Animal consumption       Both

### Firm Operations

21. What products does your facility process?

22. Enter the manufacturing process the Firm uses (i.e. canning, freezing, packing/repacking):

23. Describe your Firm's manufacturing process (raw material to finished product):

24. Is your facility a vessel (boat/ship)?

- Yes                       No

25. What is the date and product/commodity last shipped to the United States?

26. Are you a supplier (do you sell bulk products for further processing)?

- Yes                       No

If "Yes", list product:

27. List Name/Address of any company that provides manufacturing/processing services for your products:

28. What is the US FDA Food Facility Registration (FFR) associated with your manufacturing location?

29. Does your Firm have additional buildings at the inspectional location?

- Yes                       No

If "YES", answer the following questions:

i. Can you walk to this building from the manufacturing address?

- Yes                       No

ii. Please list the activities of each building:

30. Has this Firm location been inspected by US FDA before?

- Yes                       No

If "YES", please provide dates of inspection and any actions:

31. Has your Firm had any of the following in the past 3 years?

- Consumer Complaints       Import Alerts                       Recalls

Please provide date(s):

## Inspection Information

32. Contact information for the most responsible person:

i. Name :

ii. Title:

iii. Email Address:

iv. Phone/mobile cell number (include country code):

33. Local point of contact during inspection:

i. Name :

ii. Title:

iii. Email Address:

iv. Phone/mobile cell number (include country code):

34. US Agent contact information:

i. Name :

ii. Title:

iii. Email Address:

iv. Phone/mobile cell number (include country code):

35. Do you have an English speaking employee or firm representative who can assist with translation, interpret documents, and explain manufacturing operations during the inspection?

Yes

No

If "NO", what is the official language spoken by facility personnel and management?

36. What is the best mode of transportation to your Facility?

37. Is your Facility willing to provide transportation for the inspector from their hotel to your Facility and return?

Yes

No

38. Is your Facility willing to provide transportation for the inspector from the airport to their hotel and return?

Yes

No

## Additional Information

Use this area to add information that would not fit in the designated section (please list the question number):



## Recommendation(s) for Hotel, Airport, Taxi, and Rail

### Recommended Hotels

Hotel Name:

Street Address:

City, State/Province/Area, Country/Zip Code:

Telephone:

Fax:

Website:

Cost per night:

Approximate travel time to your Facility:

Hotel Name:

Street Address:

City, State/Province/Area, Country/Zip Code:

Telephone:

Fax:

Website:

Cost per night:

Approximate travel time to your Facility:

### Recommended Airport

Airport name (airport code):

Approximate travel **time** to hotel from closest airport:

Approximate travel **distance** to hotel from closest airport:

### Recommended Taxi Service

Taxi Service Name:

Telephone:

Website:

### Recommended Rail/Train

Train station name (code):

Street Address:

City, State/Province/Area, Country/Zip Code:

Telephone:

Website:

### Additional Travel Information/Recommendations

Use this area to add additional travel information or recommendations: