

for

FOREIGN & DOMESTIC FACILITIES



O V E R V I E W of R E G U L A T I O N S

Title 21 of the United States (*U.S.*) Code of Federal Regulations (*C.F.R*), Chapter I, Subchapter A, Part 1, Subpart H and Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (*Bioterrorism Act*) require that all domestic and foreign facilities that are engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption, register with the U.S. Food and Drug Administration (*FDA*). Registration must occur: 01) before the facility begins to manufacture, process, pack, or hold food for consumption in the U.S., and 02) bi-annually thereafter. Bi-annual registration, also known as "renewal" registration, must be submitted to the FDA during the period beginning October 1 and ending December 31 of each even-numbered year (*e.g.* 2022).

INSTRUCTIONS

Please complete the following sections to the best of your ability and with as much detail as possible. All sections are required, unless explicitly noted otherwise. Complete form via computer, **do not print**. Once complete, please return form via e-mail to info@unitedsafetyagents.com.

DUNS NUMBER

All facilities must have a DUNS® Number to register with the FDA. To check if your facility already has a DUNS, please visit fdadunslookup.com. To obatin a DUNS, please review the FDA DUNS Portal User Guide.

CONFIDENTIALITY

All information shared will remain strictly privileged and confidential and will ONLY be used during FDA Facility Registration. This document may contain non-binding recommendations. For additional information about our strict Confidentiality Policy, please visit unitedsafetyagents.com/confidentiality. United Safety Agents LLC (USA) provides U.S. FDA compliance services to industry and has no direct affiliation with the U.S. FDA.

CONTACT

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com; Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; UnitedSafetyAgents.com, or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.



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| TY | PE of FDA REGISTRA | TION | | |
|---|---|---------------------------------------|--------------------|------|
| ☐ Bi-Annual / Renewal Registration | if Bi-Annual , provide the | following information. | | |
| ☐ Initial FDA Registration | nitial FDA Registration FDA Registration No: | | | |
| C O M P A | NY / FACILITY INFO | RMATION | | |
| Company Name: | | Today's Date: | | |
| Legal Entity Type: | | Other: | | |
| Facility Address: | | Line 2: | | |
| City: | Province: | Country: | | |
| Phone No.: | E-mail: | DUNS No.: | | |
| Is Mailing Address different from Facility | y Address? if yes, provide the f | ollowing information | □Yes | □No |
| Mailing Address: | | Line 2: | | |
| City: | Province: | Country: | | |
| Phone No.: | Fax No.: | E-mail: | | |
| Name of Individual or Entity: Street Address: City: Phone No.: | Province: | Line 2: Country: E-mail: | | |
| Individual Name: | | | | |
| | | Title: | | |
| Phone No.: | E-mail: | Title: | | |
| Phone No.: | E-mail: NT COMPANY / TRAD | | if applica | ble |
| Phone No.: | NT COMPANY / TRAD | E NAMES | | able |
| Phone No.:PAREI | NT COMPANY / TRAD | E NAMES | if applica | |
| Phone No.: PARE I Is company/facility part of a parent com | NT COMPANY / TRAD pany? I if yes, provide the foil | E NAMES Ilowing information | if applica □Yes | □No |
| Phone No.: PARE I Is company/facility part of a parent com Name of Parent Company: | NT COMPANY / TRAD pany? I if yes, provide the foil | E NAMES Ilowing information Line 2: | if applica □Yes | □No |

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| Company Name: | Todav's Date: |
|---------------|---------------|
| .ompany Name* | TOGAV S DATE: |
| | |

PRODUCT / ACTIVITY for HUMAN CONSUMPTION

| | | | | | | er | | | | |
|------------------------------------|---------------------|--|-------------------|--------|---------|------------|---------|---------|------|----------------|
| Categories of Human Food | nufactu Low Acid | | 7arehou 33-55° | Packer | Labeler | Sterilizer | Caterer | Salvage | Farm | Other see pg 7 |
| | | | | | | | | | | |
| Alcoholic beverages | | | | | | | | | | |
| Baby food | | | | | | | | | | |
| Bakery | | | | | | | | | | |
| Beverage bases | | | | | | | | | | |
| Candy or gum | | | | | | | | | | |
| Cereal, breakfast | | | | | | | | | | |
| Cheese | | | | | | | | | | |
| soft, ripened cheese | | | | | | | | | | |
| semi-soft cheese | | | | | | | | | | |
| hard cheese | | | | | | | | | | |
| other cheese | | | | | | | | | | |
| Chocolate or cocoa | | | | | | | | | | |
| Coffee or tea | | | | | | | | | | |
| Color additives | | | | | | | | | | |
| Dietary conventional | | | | | | | | | | |
| Meal replacements | | | | | | | | | | |
| Dietary supplements | | | | | | | | | | |
| proteins, amino acids | | | | | | | | | | |
| vitamins or minerals | | | | | | | | | | |
| animal by-products | | | | | | | | | | |
| animal extracts | | | | | | | | | | |
| herbals or botanicals | | | | | | | | | | |
| Dressing or condiment | | | | | | | | | | |
| Eggs or Shell egg | | | | | | | | | | |
| chicken egg products | | | | | | | | | | |
| other egg products | | | | | | | | | | |
| Fishery or Seafood | | | | | | | | | | |
| fin fish, whole, or filet | | | | | | | | | | |
| molluscan shellfish | | | | | | | | | | |
| other shellfish | | | | | | | | | | |
| ready-to-eat | | | | | | | | | | |
| processed or other | | | | | | | | | | |
| | | | | | | | | | | |

| 7 NT NT | Todav's Date: |
|---------------|---------------|
| Company Name: | TOUSK'S DSTE. |
| dompany mame. | Today 5 Date. |

PRODUCT / ACTIVITY for HUMAN CONSUMPTION

| Categories | | nufactu Low Acid | | | arehou | 1se ∣ >55°F | Packer | Labeler | Sterilizer | Caterer | Salvage | arm | Other |
|-----------------------------|---------|----------------------------|-----------|------|---------|-----------------------|--------|---------|------------|---------|---------|-----|----------|
| of Human Food | general | LOW ALI | acidified | <0°C | 01-13°C | >13°C | Pa | La | St | Ü | Sa | Б | see pg 7 |
| Food additives | | | | | | | | | | | | | |
| GRAS ingredients | | | | | | | | | | | | | |
| processing ingredients | | | | | | | | | | | | | |
| Food sweeteners | | | | | | | | | | | | | |
| Fruit or fruit products | | | | | | | | | | | | | |
| fresh cut produce | | | | | | | | | | | | | |
| raw agricultural comm. | | | | | | | | | | | | | |
| other | | | | | | | | | | | | | |
| Fruit or vegetable juice | | | | | | | | | | | | | |
| Gelatin, pie fillings, etc. | | | | | | | | | | | | | |
| Ice cream | | | | | | | | | | | | | |
| Imitation milk products | | | | | | | | | | | | | |
| Noodle products | | | | | | | | | | | | | |
| Meat or poultry | | | | | | | | | | | | | |
| Milk, butter, etc. | | | | | | | | | | | | | |
| Multiple food dinners | | | | | | | | | | | | | |
| Nuts or seed products | | | | | | | | | | | | | |
| edible seed products | | | | | | | | | | | | | |
| Prepared salad products | | | | | | | | | | | | | |
| Chicken egg products | | | | | | | | | | | | | |
| other egg products | | | | | | | | | | | | | |
| Snack food items | | | | | | | | | | | | | |
| Spices, flavors, or salts | | | | | | | | | | | | | |
| Soups | | | | | | | | | | | | | |
| Soft drinks or waters | | | | | | | | | | | | | |
| Vegetable products | | | | | | | | | | | | | |
| fresh cut vegetables | | | | | | | | | | | | | |
| raw agricultural comm. | | | | | | | | | | | | | |
| other vegetable products | | | | | | | | | | | | | |
| Vegetable oils | | | | | | | | | | | | | |
| Simulated meats | | | | | | | | | | | | | |
| Miller grain products | | | | | | | | | | | | | |
| None of the above | | | | | | | | | | | | | |

| Company Name: | any Name: Today's Date: | | | | | |
|--|--------------------------------------|------------------------------|---------------------------|--|--|--|
| | OTHER PRODUCTS / A | ACTIVITIES | if applicable | | | |
| If you selected <i>None of the abo</i> | ove for any Product Category, or O | Other for any Activity, plea | se provide context about | | | |
| the product(s) that facility han | dles, and/or the activity that facil | ity performs below. Includ | e whether product(s) are | | | |
| for Human or Animal consumpt | tion. | | | | | |
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| | End of Question | ıs | | | | |
| | | | | | | |
| | | | | | | |
| | CERTIFICAT | I O N | | | | |
| ☐ I agree that FDA will be per | mitted to inspect the facility at th | e time and manner permit | ted by the FD&C Act* | | | |
| ☐ By authorizing USA to subr | nit this form to FDA and function | as my facility's properly d | esignated and qualified | | | |
| U.S. Agent, I certify that the | e above information is true and ac | curate. Further, I agree to | all terms of service, and | | | |
| acknowledge that an annua | l fee of 349 USD is applicable to th | nese services* | | | | |
| ☐ I understand that FDA Food | l Facility Registration and U.S. Ago | ency is distinct from Forei | gn Supplier Verification | | | |
| Program (FSVP) compliance | e and agree not to name USA as my | y company's FSVP Importe | er, unless USA has sepa- | | | |
| rately agreed in writing to f | function in such capacity* | | | | | |
| | | | | | | |
| | AUTHORIZING IND | OIVIDUAL | | | | |
| Name of Authorizing Individua | 1: | | | | | |
| Title: | Signature: | | | | | |
| Street Address: | | Line 2: | | | | |
| City: | Province: | Country: | | | | |
| Phone No.: | Fax No.: | E-mail: | | | | |