



US Agent Services: Guiding You Through Every Step of Compliance

20241015

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Scope:

- ✓ **US Agent Services**

Deliverable:

The Agent shall provide the following services on behalf of the Foreign Entity:

Acts as a liaison or communication link between the Foreign Entity and “Regulatory Authorities” in the United States, including the U.S. Food and Drug Administration (FDA), United States Department of Agriculture (USDA) and Federal Trade Commission (FTC):

- Serving as the primary point of contact between the foreign food facility and the Regulatory Authorities to ensure coordination;
- Receiving communications from the Regulatory Authorities on the designated U.S. agent’s United States address and/or email, including regulatory notifications such as inspection notices or compliance inquiries;
- Transmitting information from the regulatory body(ies) to the Foreign Entity, ensuring that the information is promptly and accurately relayed.
- Facilitating response to the Regulatory Authorities’ requests for information (e.g., third-party certifications, food safety plans, supply-chain records) or actions to correct non-compliance issues (e.g., response letters, CAPA reports);
- Keeping the Regulatory Authorities up-to-date with the U.S. agent contact information (e.g., U.S. address, email address, phone number), as well as the foreign facility’s information; and
- Ensuring prompt delivery of these communications and changes to the foreign food facility.

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Deliverable (cont...):

Assists in regulatory enforcement actions and emergency situations that may arise in relation to food safety issues including, but not limited to, Regulatory Authorities-initiated inspections, product recalls, detentions, and food safety-related issues, with the U.S. agent ensuring prompt execution of the following:

- Ensuring that the foreign facility is notified about the inspection, and helping the Foreign Entity ensure that the necessary logistical arrangements are set and scheduled for the authorities to access the facility; and
- Initiating timely and proper communication with its customers, partners, stakeholders, and regulatory and certification bodies in the United States in any event of a recall, detention, and complaints facilitated by the Regulatory Authorities; and
- Serving as the point of contact to provide timely communication and to ensure swift responses to address potential public health risks associated with the food product.

Assists the Foreign Entity in complying with applicable laws and regulation requirements in the United States, including but not limited to:

- Food Safety Modernization Act (FSMA) of 2011 Compliance; and
- Supply Chain Program Compliance

Provides any additional services mutually agreed upon by the parties in writing.

Service Fee:

\$99.00/month (month-to-month)

Subscription link: <https://consultareinc.com/shop/us-agent-services/>

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