

FDA Facility Registration Frequently Asked Questions

- Q. Are food facilities outside the United States required to register with the U.S. Food and Drug Administration (FDA)?
- A. Yes, under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* ("The Bioterrorism Act"), the U.S. Congress requires that FDA register all facilities that manufacture, process, pack, or hold food for consumption in the U.S.
- Q. What is the definition of food?
- A. The definition of food under FDA regulations includes any article used in foods or drinks as well as all ingredients used to make them.
- Q. Are essential oils considered food?
- A. If the essential oil can be used in a food then it is considered food under this regulation.
- Q. Which facilities must register?
- A. Facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register. Facilities outside the U.S. that engage in these activities are required to register unless food from that facility undergoes further processing or packaging by another foreign facility before the food is exported to the United States. However, if the subsequent facility outside the U.S. performs only a minimal activity, such as putting on a label, both facilities would be required to register.
- Q. What does FDA mean by "hold"?
- A. Holding food means storage of food.
- Q. Who is responsible for registering a facility?
- A. Owners, operators, or agents in charge of domestic or overseas facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register their facility with the FDA.

- Q. If our company has multiple facilities do we have to register each of them or do we simply register the company name?
- A. The registration requirement is facility specific; each facility requires a separate registration. However, one U.S. agent can represent multiple facilities.
- Q. Are farms and restaurants required to register?
- A. No, the following types of facilities are exempt from registration: farms; retail food operations; restaurants; non-profit operations that prepare food for, or serve food directly to, consumers; fishing vessels not engaged in processing; and facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture.
- Q. Are all foreign facilities, i.e., facilities outside the U.S., required to register?
- A. No, a foreign facility is exempt from registering if food from the facility undergoes further processing (including packaging) by another facility outside the U.S. The first facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to affixing a label to a package or other *de minimis* activity. The facility that conducts the *de minimis* activity also must register.
- Q. Which facilities must designate a U.S. agent?
- A. Facilities located outside the United States must designate a U.S. agent for their facility. Verto Solutions, LLC Facility Registration can serve as the agent for your facility.
- Q. What is the role of the U.S. agent?
- A. Your U.S. agent's responsibility to contact the facility and pass on information from FDA in both emergencies and routine operations. In addition, your agent may complete the on-line registration of your facility. The U.S. agent is not expected to have information about the shipments a facility sends to the United States.

U.S. agent means a person residing or maintaining a place of business in the U.S. whom a foreign facility designates as its U.S. agent for the purpose of registration regulation. The U.S. agent acts as a communications link between FDA and the foreign facility. Having a single U.S. agent for the purposes of registration does not preclude facilities from having multiple agents for other business purposes. A firm's commercial business in the U.S.

need not be conducted through the U.S. agent designated for registration purposes.

Q. What are the fees for registration?

A. There is no fee to register your facility with the FDA. However, Verto Solutions, LLC Facility Registration charges \$550.00 (U.S.) annually to serve as your U.S. based agent and to register your facility. If you are registering multiple facilities, the fee for the first facility will be \$550.00 annually, with \$165.00 annually for each additional facility. As part of our agent services, we will also complete the registration of your facility.

A. Failure to register is a prohibited act under the Federal Food, Drug and Cosmetic Act. The U.S. government can bring a civil action in court to enjoin persons who commit a prohibited act. If overseas facilities fail to register and also attempt to import food into the U.S., The Bioterrorism Act requires that the food be held at the port of entry unless FDA directs that it be moved to a secure location.

Q. Will I have to notify Verto Solutions, LLC Facility Registration every time I ship food into the U.S.?

A. No, Verto Solutions, LLC Facility Registration does not have to be notified when you ship food into the U.S. After you complete the initial registration form, Verto Solutions will not need to collect any additional information from you. The registration form will ask you to provide information about the general food product categories of your products, but there will not be any questions about specific transactions, including customer or supplier information.

Q. What is the difference between the registration requirement and prior notice to import food?

A. The U.S. FDA has published two final bioterrorism regulations. One requires food facilities to register with the FDA. A second regulation requires prior notice to import food into the U.S. For more information on the prior notice requirement, visit the FDA bioterror web site at:
<http://www.fda.gov/oc/bioterrorism/bioact.html>.

Q. Why should we select Verto Solutions, LLC Facility Registration as our U.S. agent?

A. Verto Solutions has a team of professionals experienced in FDA compliance matters. Our clients benefit from our in-depth understanding of food and cosmetic laws and regulations. The global food industry is familiar with Verto Solutions' work on behalf of food additive importers and exporters. In

addition, our fees are substantially lower than those estimated by the FDA. For more information on Verto Solutions, LLC, go to: www.vertosolutions.net.

- Q. If I have additional questions about the FDA regulations or Verto Solutions' services, whom can I contact?
- A. If you have additional questions about FDA Food Facility Registration or Verto Solutions contact us at ++202-293-5800 or email us at registrations@vertosolutions.net.

