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Food

Clarification Letter Sent to Food Facilities Registered Under the Bioterrorism Act - U.S. Agents Have No Affiliation With the U.S. FDA

CFSAN



Constituent Update

Center for Food Safety and Applied Nutrition • Food and Drug Administration

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The United States Food and Drug Administration (U.S. FDA) has sent by e-mail a letter to owners and operators of food facilities registered with the U.S. Food and Drug Administration pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the agency's implementing regulation, the Registration of Food Facilities Final Rule (21 CFR §§ 1.225-1.243). The e-mail contained links to allow food facility owners and operators to view the U.S. FDA letter in English, French, and/or Spanish.

U.S. FDA's Registration of Food Facilities Final Rule requires owners and operators of all domestic and foreign facilities that manufacture, process, pack, or hold food that will be consumed in the United States to register with U.S. FDA. Registrations for foreign facilities must contain the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated in the registration) who resides or maintains a place of business in the United States. (21 CFR §§ 1.227(b)(13) and 1.232(d)).

U.S. FDA sent its letter in response to an inquiry the agency received from a foreign embassy seeking clarification on information that had been sent to a number of food facilities in its country by FDA Registrar Corporation (FDA Registrar Corp). U.S. FDA is aware that private businesses, such as FDA Registrar Corp., are offering their services to food facilities. The purpose of U.S. FDA's response is to clarify that these private businesses are **not** affiliated with U.S. FDA, nor do they act on U.S. FDA's behalf.

U.S. FDA's letter to facility owners and operators also notes the following regarding the registration of food facilities:

1. Food facilities can register directly with U.S. FDA. There is no fee to register with U.S. FDA.

A food facility may register, update, or cancel its registration itself (or authorize another person to do so on its behalf) using the Internet at <http://www.access.fda.gov>¹. Alternatively, a food facility may register, update, or cancel a registration by mail by requesting the appropriate form from U.S. FDA at 1-800-216-7331 (301-575-0156 outside the United States), or by e-mail at furls@fda.gov.

U.S. Agents may charge a fee for their services, which is solely an issue to be decided between the food facility and the person who agrees to serve as the food facility's U.S. Agent.

2. Contrary to any suggestion by FDA Registrar Corp., food facilities should register only once. The registration does not expire.

If any of the mandatory information in a registration changes (e.g., a food facility changes U.S. Agents or food product categories manufactured at the facility), the registered food facility must update the registration within 60 days of the change. 21 CFR § 1.234. The registered food facility must cancel a registration within 60 calendar days of the reason for cancellation (e.g., facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner). 21 CFR § 1.235

3. Contrary to any suggestion by FDA Registrar Corp., food facilities do not need a certificate of registration.

U.S. FDA does not issue a certificate of registration, nor does U.S. FDA recognize a certificate of registration issued by a private business. U.S. FDA issues a registration number to registered facilities. Any registered food facility may obtain its registration number by contacting U.S. FDA.

4. Contrary to any suggestion by FDA Registrar Corp., food facilities that have registered and do not have their FURLS information or PIN should not re-register. Instead, a food facility can contact U.S. FDA for help at 1-800-216-7331 (301-575-0156 outside the United States), or by e-mail at furls@fda.gov.

A food facility will be asked to provide information on its company's letterhead signed by the owner, operator, or agent-in-charge of the facility to verify the information. Once U.S. FDA verifies the identity of the food facility, U.S. FDA will provide the facility access to its account. For more information about these requirements, please refer to the Final Rule and to U.S. FDA's website (The Bioterrorism Act of 2002) for Question and Answer guidance documents, tutorials, and other information. You can also ask U.S. FDA for help at 1-800-216-7331 (301-575-0156 outside the United States), or by e-mail at furls@fda.gov.

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