



News & Types: Commercial, Competition & Trade Update

FDA Renewal Due for Food Facilities at End of 2018

9/28/2018

Practices: Commercial, Competition & Trade

This year, all food facilities required to register with the FDA must renew their registrations by the end of the year. It is important to note that even food facilities that just got registered in 2018 must “renew” their registration this year. Renewal can be done online through the FDA website through its FDA Industry Systems at <https://www.access.fda.gov/>.

Facilities, both domestic and foreign, that manufacture, process, pack or hold food for human or animal consumption in the United States must register with the U.S. Food and Drug Administration (“FDA”). On each even-number year, all food facilities are required to renew their FDA registrations during the period beginning on October 1 through December 31. If any information in the registration changes, the FDA must be notified and updated in a timely manner. No fees are charged for registration, renewals, and updates.

If a food facility fails to register, renew, or update its registration, it (1) is prohibited from manufacturing, processing, packing, or storing food that may be consumed in the U.S. until it obtains a new registration, and (2) may be subject to civil and/or criminal action by the federal government. The original registration cannot be reinstated by any means.

The scope of the registration requirement is quite broad and covers many businesses in the food industry. “Food” is defined under the Federal Food, Drug, and Cosmetic Act (the “Act”) as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” Some examples of such “food” provided by FDA’s guidelines include dietary supplements and dietary ingredients, infant formula, beverages (including alcohol and bottled water), fruits and vegetables, fish and seafood (except for fish of the order Siluriformes, i.e., catfish, tra, swai, and basa, which are regulated by the U.S. Department of Agriculture), dairy products and shell eggs, raw agricultural commodities for use as food or food components, canned and frozen foods, bakery goods, snack food and candy, live food animals, pet food and treats, and animal feed. Food contact substances and pesticides are not “food” and thus facilities that manufactures, processes, packs, or stores such items do not need to register with the FDA.

The term “facility” includes “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.” Farms, restaurants, and other retail food establishments, nonprofit food establishments, and fishing vessels are explicitly excluded from the definition of “facility.” Other examples provided by FDA’s guidelines on facilities that do not have to register include private residences, non-bottled water and water distribution establishments, and transport vehicles that

hold food only in the usual course of business as carriers. In terms of food industry sector, domestic and foreign manufacturers, processors, packers, and storage operators are affected by the Act.

The FDA requires this registration because the government views these food facilities as potential targets for bioterrorism, and identifying the location of all such potential targets will help the government prepare for and respond to this type of terrorism. Registration will also help the FDA determine the location and source of potential outbreaks of food-borne illness and notify facilities that may be affected. Any terrorism against livestock and crop and public health emergencies can be destructive to U.S. social, economic, and political stability and agricultural infrastructure, and this FDA registration requirement for food facilities is one of many efforts of the U.S. government to protect the U.S. from such potential catastrophes.