

ALERTS

FDA Amends Final Rule On Registration Of Food Facilities

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The Food and Drug Administration (FDA) recently amended its final rule on the registration of food facilities. Food facilities in the United States and internationally that manufacture/process, pack or hold food for consumption in the U.S. are required to register with the FDA and the amended rule adds new provisions to codify certain provisions of the Food Safety Modernization Act. Those provisions include the requirement to provide an email address for registration, to renew a registration every two years, and to include an assurance that the FDA will be permitted to inspect the facility at the times and in the manner permitted by the federal Food, Drug and Cosmetic Act.

In addition, as of July 14, 2016, when the final rule went into effect, registrations are now required to contain the type of activity conducted at the facility for each food product category. The final rule also amends the definition of a retail food establishment in a way that expands the number of establishments that are considered retail food establishments and are therefore not required to register with the FDA as food facilities. Of course, all food establishments, including retail food establishments, continue to have a responsibility to ensure their food is safe.

All food facility registrations are required to be submitted to the FDA electronically, although this requirement does not take effect until Jan. 4, 2020.

According to the FDA, the amended rule will better protect public health by requiring additional registration information that will improve the accuracy of the food facility registration database for facilities both in the U.S. and abroad. The FDA claims the final rule will support its efforts to act quickly in response to food-related emergencies and will help it use its inspectional resources more efficiently.

A copy of the Federal Register notice for the final rule can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; or Alicia Raines Barrs at (317) 231-7398 or alicia.rainesbarrs@btlaw.com.

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