BARNES & THORNBURG LLP

ALERTS

Food, Drug And Device Law Alert - Updated, Expanded Guidance Issued For Food Facility Registration

November 18, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

As we reported here earlier this year, the Food and Drug Administration (FDA) amended its final rule on the registration of food facilities. The amended rule includes the requirements 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 expands the number of establishments that are considered retail food establishments and are therefore not required to register with the FDA as food facilities.

Recently, to assist companies in their efforts to comply with the amended final rule, the FDA has issued a new, expanded Seventh Edition of its guidance document titled "Questions and Answers Regarding Food Facility Registration." The guidance adds a number of new questions and answers, such that it is impractical to list and discuss all of them. However, the categories with one or more new questions and answers are:

- Biennial registration renewal
- Abbreviated registration renewal process
- Electronic registration and registration renewal
- Unique facility identifier and verification procedures
- Verification procedures for changes not made by the owner, operator, or agent in charge
- Verification procedures for U.S. agents
- Requirement to update incorrect registration information
- Unique facility identifier
- Food product categories
- Activity type information
- Requirement to provide assurance that FDA will be permitted to

RELATED PEOPLE

Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

RELATED PRACTICE AREAS

Food, Drug and Device Law

inspect

- How and when to update your facility's registration information
- How and when to cancel your facility's registration information
- The consequences of failing to register, renew, update, or cancel your registration
- Waiver requests
- General questions
- Compliance dates

In addition, some of the answers to existing questions were revised.

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; Elizabeth Davis at (404) 264-4025 or beth.davis@btlaw.com; or Alicia Raines Barr at (317) 231-7398 or alicia.rainesbarr@btlaw.com.

Visit us online at www.btlaw.com/food-drug-and-device-law-practices.

Visit us online at www.btlaw.com and follow us on Twitter @BTLawNews.