

ALERTS

Food, Drug And Device Law Alert - Effective Immediately: FDA Adds More Food Categories To Registration Of Food Facilities

October 11, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a final guidance identifying additional categories of food from which food companies will be required to select when completing their facility registrations. Importantly, because the statute authorizes the FDA to create these categories "through guidance," this guidance document is now binding on companies.

The guidance further implements provisions of the Bioterrorism Act from 2002 and Food Safety Modernization Act of 2011 to protect the nation's food supply. The guidance states that "FDA believes that information about a facility's food categories is a key element to allow for rapid communications between the FDA and facilities directly impacted by actual or potential bioterrorist attacks, other food-related emergencies, or food safety incidents."

With respect to food intended for human consumption, the guidance adds the following categories to the registration process:

- Acidified Food (see 21 CFR 114.3(b));
- Cheese and Cheese Product Categories: Soft, Ripened Cheese;
 Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products;
- Dietary Supplement Categories: Proteins, Amino Acids, Fats and Lipid Substances; Animal By-Products and Extracts; Herbals and Botanicals;
- Fisher/Seafood Product Categories: Fin Fish, Whole or Filet; Shellfish; Ready to Eat (RTE) Fishery Products; Processed and Other Fishery Products:
- Fruit and Fruit Products: Fresh Cut Produce; Raw Agricultural Commodities; Other Fruit and Fruit Products;
- Fruit or Vegetable Juice, Pulp or Concentrate Products;
- Low Acid Canned Food (LACF) Products (see 21 CFR 113.3(n));
- Nuts and Edible Seed Product Categories: Nut and Nut Products; Edible Seed and Edible Seed Products;
- Shell Egg and Egg Product Categories: Chicken Egg and Egg Products; Other Egg and Egg Products;
- Vegetable and Vegetable Product Categories: Fresh Cut Products; Raw Agricultural Commodities; Other Vegetable and Vegetable Products; and
- Baby (Infant and Junior) Food Products Including Infant Formula.

In addition, the guidance adds several categories of food for animal consumption, most of which it notes are already included as options.

A copy of the guidance 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

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