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Food Safety Modernization Act Registration Requirements Begin October 1, 2012 for All Food Facilities

By Sandra Liss Friedman and Helena D. Sullivan

Starting on October 1, 2012, U.S. and foreign food facilities that sell into the U.S. market will be required to comply with the new registration process established by the Food Safety Modernization Act (FSMA). Although FSMA became law in January of 2011, amending the Food, Drug and Cosmetic Act significantly in order to strengthen the food safety system, the amendments relating to food facility registration are taking effect after the 2 year grace period established under the law. Under section 102 of the FSMA, the new registration requirement will replace the current registration requirement under section 415(a)(2) of the Food Drug and Cosmetic Act. Under the FSMA, food facilities are subject to a biannual registration period from October 1 to December 31 of each even-numbered year. Any facility that manufactures, processes, packs or holds food within the United States, and foreign food facilities that export to the United States, must register with the FDA during this period. All facilities that registered under section 415(a)(2) are required to renew their registration no later than December 31, 2012. New facilities that begin to sell or export to the United States after December 31, 2012 must file their initial registration as soon as they begin to sell and renew registration at the next biannual period which would begin in October 2014.

The new registration adds several new elements to the previous information required by the FDA, including email addresses for the contact person at the U.S. facility; for a foreign facility, the email address of the United States agent must be provided, and an assurance that FDA will be permitted to inspect the facility. There may be other information required as FDA deems necessary. Registrations may be submitted online, by mail or fax.

FSMA also gives the FDA new powers to enforce food safety. For the first time, FDA has the authority to suspend the registration of a food facility when food manufactured, processed, packed, received or held by that facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. To make such a suspension, FDA has to show that the facility was responsible for the health issue in question, or knew of it and packed, received or held the food anyway. Facilities that are suspended may not import into the United States or otherwise introduce their food into U.S. commerce.

Facilities that register must be in compliance with the FSMA requirements for a written, auditable food safety plan, including hazard analysis and risk-based preventive controls, although there are certain exemptions. FSMA requires the FDA to allocate resources to food inspection based on a given facility's risk profile, and to increase inspection frequency.

However, FSMA also provides for the establishment of a voluntary qualified importer program, to allow expedited review and importation of food by importers who participate and have their facilities certified under the program, as well as a foreign supplier verification program. While FDA has drafted a proposal for these programs, the proposal is currently under review by other agencies and it will be some time before they are enacted.

Under the FSMA, the FDA also has new powers to force recall of hazardous, adulterated or misbranded products. It also allows the FDA to administratively detain food if FDA has "reason to believe" that the food is adulterated or misbranded.

As these new registration requirements take effect and enforcement by the FDA is increased, companies should ensure that their food safety plans are adequate to meet the new obligations. Please contact our office if you have any questions about this new law.