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Food, Drug & Device Law Alert - FDA Proposes To Amend Regulations On Food Facility Registration

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The Food and Drug Administration (FDA) recently published a Notice of Proposed Rulemaking in the Federal Register concerning the regulations on food facility registration. The proposed regulation would implement certain provisions of the Food Safety Modernization Act (FSMA) related to registration of food facilities. In addition, FDA states that the proposed regulation would amend and update FDA's registration regulations to enhance its ability to respond to food-related emergencies and to better use its limited inspection resources.

FSMA included several self-implementing provisions related to food facility registration that became effective upon passage of FSMA in January 2011. The proposed regulation will codify these provisions, including:

1. requiring registrations for domestic food facilities to contain the email address for the contact person of the facility and registrations for foreign food facilities to contain the email address of the U.S. agent for the facility;
2. requiring food facilities to renew their registrations with FDA every two years, between October 1 and December 31 of each even-numbered year, by submitting registration renewals; and
3. requiring all food facility registrations to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.

Additionally, the proposed rule will implement FSMA's requirement for all food facilities to submit their registrations to FDA in an electronic format. Under FSMA, this requirement cannot take effect before January 4, 2016.

As required by FSMA, the proposed rule would amend the definition of "retail food establishment" in 21 CFR § 1.227(b)(11). A retail food establishment is one that primarily sells food directly to consumers. The amended definition would clarify that, in determining the primary function of an establishment or a retail food establishment, the sale of food products directly to consumers includes:

1. The sale of food products or food directly to consumers at a roadside stand or farmers' market where the stand or market is located other than where the food was manufactured or processed;
2. the sale and distribution of food through a community supported agriculture program; and
3. the sale and distribution of food at any other direct sales platform allowed by FDA.

Finally, the proposed rule seeks to improve the usefulness of the food

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facility registration database. The rule would require certain additional data in food facility registrations, employ additional measures to verify certain information submitted in registrations, and give FDA the authority to cancel a registration in a number of additional circumstances, including the failure to renew a registration timely.

A copy of the final guidance document can be found [here](#). Interested parties can submit comments until June 8.

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 Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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