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E-ALERT | Food & Drug

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FDA BEGINS BIENNIAL REGISTRATION RENEWAL

FDA announced late on Friday, October 19 that it would begin the biennial registration renewal process for food facilities on Monday, October 22.

As we explained in our client alerts of October 4 and September 27, the FDA Food Safety Modernization Act ("FSMA") specified that a facility's registration must be renewed biennially during the period beginning on October 1 and ending on December 31 on even-numbered years. FDA is required to provide for an abbreviated process for facilities that do not have any new information to report. In addition to the renewal requirement, the FSMA also specified that facilities must provide the email address for a contact person, and the registration must contain "an assurance that [FDA] will be permitted to inspect such facilities at the times and manner permitted by" the Federal Food, Drug, and Cosmetic Act.

FDA announced on Friday, September 28, 2012 that it would not be able to accept registration renewals on Monday, October 1. During a conference call with stakeholders, Amy Barringer, Director, Division of Field Programs and Guidance, FDA Center for Food Safety and Applied Nutrition (CFSAN), did not explain the specific reason for the delay or provide an estimate of when the renewal system would become available. Ms. Barringer also said that, once the renewal module becomes available, FDA was considering providing a three-month registration window in light of the three-month window provided for by the FSMA, but that the agency had not made a final decision on this issue.

In conjunction with opening the registration renewal process, FDA released updated "Frequently Asked Questions" about registration. The updated FAQ webpage answers questions regarding the mechanics of registration and renewal. Although the FAQ page notes that registration begins on October 22, it does not specify when the registration period will close. The FAQ page indicates that FDA will release a guidance document on registration "to further clarify the process." Consistent with statements made during the October 1 conference call, it appears that FDA will not, at this time, collect the voluntary information FDA proposed in a May 11, 2012, Federal Register notice.

FDA also released a final version of "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories." The Guidance expands the list of food categories required to be included in the registration. The only substantive change to the document appears to be the addition of the instructions to the section on human food categories, "[i]f none of the human food categories listed in the registration form apply, print the applicable food category or categories." The draft guidance featured these instructions in conjunction with animal foods only.

Additionally, FDA updated its "step-by-step" instructions for online registration, which indicate that facilities renewing a registration online will be able to review a prepopulated form. FDA indicated that registrants also may renew by submitting a paper or CD-ROM version of FDA Form 3537, but the

form is dated August 2011 and does not appear to be updated to capture the new mandatory fields added by the guidance document discussed above.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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