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E-ALERT | Food & Drug

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FDA DELAYS BIENNIAL REGISTRATION RENEWAL

The Food and Drug Administration announced late on Friday, September 28 that, contrary to earlier statements, food facilities would not be able to renew their registrations on October 1.

As we explained in a client alert on September 27, the FDA Food Safety Modernization Act ("FSMA") specified that a facility's registration must be renewed biennially during the period of October 1 and December 31 on even-numbered years, presumably under the rationale that this requirement will force facilities on a regular basis to assess whether their registration information is current. 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 made the announcement of the delay through an email to stakeholders on Friday evening and by posting a notice on the agency's FSMA webpage. FDA also held a conference call with stakeholders on October 1. Speaking for the agency, 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 may become available. She urged stakeholders to monitor FDA's email notices or periodically visit the FSMA webpage for updates. Ms. Barringer urged facilities to use the online module for renewal, which will feature a form prepopulated with information from prior registrations. She said that the collection of voluntary information FDA proposed in a May 11, 2012, Federal Register notice would not be available at the time registration renewal becomes active. Ms. Barringer also said that, once the renewal module becomes available, FDA is considering providing a three-month registration window in light of the three-month window provided for by the FSMA, but that the agency has not made a final decision on this issue.

Covington & Burling LLP has closely monitored FDA's implementation of the FSMA and will continue to apprise clients of important developments.

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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