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## MEMORANDUM

**From:** Gary Jay Kushner  
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**Date:** December 13, 2012

**Re:** **FDA Extends Deadline and Issues Guidance for Facility Registration Renewal**

Yesterday, the Food and Drug Administration (FDA) announced that it will exercise enforcement discretion with respect to registration renewals submitted to FDA on or before January 31, 2012. As discussed in our previous memoranda, the FDA Food Safety Modernization Act (FSMA) requires all facilities to renew their registrations with FDA between October 1 and December 31 of each even numbered year. <sup>1/</sup> FDA is extending the registration renewal deadline because the renewal system did not become active until October 22, 2012.

FDA announced the deadline extension within a new guidance document, entitled "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)." FDA updated the previous edition of this guidance to address changes made by FSMA, such as the registration renewal requirement and FDA's authority to suspend a facility's registration. In addition, FDA issued a Small Entity Compliance Guide regarding facility registration.

The updated guidance explains that failure to register or to renew, update, or cancel a registration is a prohibited act under the Federal Food, Drug, and Cosmetic Act. FDA explains that the U.S. can bring a civil action to enjoin a person who commits a prohibited act and also has the authority to bring a criminal action to prosecute a person who is responsible for the commission of a prohibited act. The agency also emphasizes that imported food cannot enter commerce until the foreign facility where the food is from has registered, although FDA's guidance does not address whether imports will be denied if an importer has failed to renew their registration.

Additionally, FDA states that the registration renewal requirement does not change the preexisting obligation for facilities to update their registration within 60 calendar days of any change to any of the required information. Finally, FDA notes that it will provide an abbreviated registration renewal process during future registration renewal cycles for facilities that have not had any changes to their registration information, as provided for by FSMA. The agency was not able to establish an abbreviated renewal process this year because all facilities needed to submit the new registration information required by FSMA.

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Should you have any questions, please do not hesitate to contact us.

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<sup>1/</sup> See Hogan Lovells memoranda dated October 22, 2012, *FDA Launches Biennial Registration Renewal System*, and September 27, 2012, *Prepare to Renew Your FDA Facility Registrations—Action Needed*.