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FDA Delays Implementation of Reportable Food Registry, Announces Draft Guidance

June 11, 2009

The Food & Drug Administration (FDA) today (June 11, 2009) delayed implementation of the Reportable Food Registry requirements of Section 417 of the Food and Drug Administration Amendments Act of 2007, Public Law 110-85 (FDAAA) to September 8, 2009. It simultaneously announced the availability of a draft guidance entitled "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007" (the "Guidance").

On September 27, 2007, President Bush signed FDAAA into law. Among other things, Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the "Act") to include a requirement that the Secretary of Health and Human Services establish within FDA a Reportable Food Registry (the "Registry") by September 27, 2008, under new Act § 417, 21 U.S.C. 350f. To further the development of the Registry, the Act also requires the FDA to establish a reportable food electronic portal for responsible parties and public health officials to use to submit to the FDA instances of reportable food by September 27, 2008. The draft Guidance, when finalized, will assist the industry in complying with these Reportable Food Registry requirements.

Read the Federal Register notice [here](#).

For More Information

We hope that this information is useful to you. If you need assistance with auditing or defending health care fraud concerns or other health care compliance, risk management, transactions or operations concerns, please contact Curran Tomko Tarski LLP Partners Cynthia Marcotte Stamer at (214) 270-2402, CStamer@CTTLegal.com; Michael T. Tarski at (214) 270-1420, MTarski@CTTLegal.com; or Edwin J. Tomko at (214) 270-1405, ETomko@CTTLegal.com.

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