May 27, 2008

FDA Delays FDAAA Reportable Food Registry Requirements

The United States Food And Drug Administration ("FDA") announced today[1] that the requirements in Section 417 of the Federal Food, Drug, And Cosmetic Act ("FDCA"), as added by the Food and Drug Administration Amendments Act of 2007 ("FDAAA") that FDA establish by September 2008 a Reportable Food Registry ("Registry") for food for which there is a "reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals" will not be implemented until Spring 2009. The FDAAA had required that FDA establish the Registry utilizing an electronic portal within one year of that act's September 27, 2007, enactment.

FDA intends to implement the section 417 requirement to establish an electronic portal for reportable food by utilizing the business enterprise system currently under development by the agency. In today's announcement, FDA "acknowledges that the prohibited act provisions relating to the Registry will not apply until such time as FDA establishes the electronic portal to implement the Registry." The "prohibited act provisions" referred to in that sentence include the failure to submit the required information to the Registry within 24 hours of determining that a food qualifies as reportable (the qualifying factors for which are, in essence, the same as those that would trigger a Class I recall of the food), the failure to provide notification to previous sources and/or subsequent recipients of the reportable food as the Secretary of Health and Human Services deems necessary, and the failure to permit FDA access and copying of all records relating to the reportable food.[2] FDAAA also requires FDA to issue guidance to industry by June 27, 2008 regarding submitting the required information to the Registry and providing notifications to other persons in the supply chain of an article of food.

FDA expects that the agency's business enterprise system will be operational in spring 2009 and will advise the public in a future issue of the Federal Register of the date the Registry requirements will be implemented. Today's notice does not indicate whether or when FDA will issue a guidance on those requirements or how much notice the agency will provide prior to implementation of the requirements.

FDA is also seeking comments, on or before August 11, 2008, regarding the general requirements contained in the Registry provisions of the FDAAA and the following questions:

> (1) What obstacles, if any, do responsible parties anticipate in complying with the requirements of section 417 of the FDCA?
> (2) How can FDA enhance the quality, utility, and clarity of the information to be submitted to the Registry?
> (3) What would be an efficient and effective method for providing and receiving notifications to and from sources and recipients in the supply chain of instances of reportable food?
> (4) In addition to the data elements set out in section 417 of the FDCA, what other information, if any, would be important to provide in responsible party notifications to the immediate previous source and immediate subsequent recipient of the article of food?

Directions for submission of comments are included in the Notice.

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[1] 73 Fed. Reg. 30405 (May 27, 2008); http://edocket.access.gpo.gov/2008/pdf/E8-11517.pdf

[2] [2] Note 1, *supra*; *see* FDCA §§ 301(e), (m).

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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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