Increasing Transparency and the Reportable Food Registry

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New Food Safety Reporting Obligations Will Take Effect on September 8, 2009, Increasing Transparency; The Electronic Portal Will Be Operational, But Essential Legal Safeguards Are Still Lacking

On June 11, 2009, the Food and Drug Administration ("FDA") Department of Health and Human Services ("DHHS") announced the availability of draft guidance on the Reportable Food Registry, which implements section 417 of the Federal Food Drug & Cosmetic Act ("FFDCA") adopted under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). In addition to providing information on who must submit a report and how, when, and where to submit reports, the guidance answers questions regarding the information that companies must submit to FDA as part of the required reports, the circumstances under which companies must notify other companies in the supply chain that a reportable food submission to FDA has been made, and other requirements concerning the operation of the electronic portal and Reportable Food Registry electronic database.

Although the draft guidance may be helpful in addressing companies' narrower questions regarding their food reporting obligations, it does not address the more fundamental and pressing need for the establishment of procedural safeguards to ensure that unverified reports of suspected food adulteration submitted to FDA's Reportable Food Registry database are held, managed, and evaluated by the agency in accordance with the governing constitutional and administrative law standards. In particular, procedural safeguards are needed to ensure that all FDA actions taken in response to reports submitted to the Reportable Food Registry are based on competent and reliable scientific evidence and are carried out in a manner that complies with the legal standards and procedures governing agency action. Such safeguards also are needed to protect the public from harms associated with unjustified public warnings and product recalls attributable to unverified reports of alleged food adulteration. Particularly in the absence of appropriate procedural safeguards, the Reportable Food Registry could contribute to significant increases in legal and business risks for responsible food companies.

While FDA's draft guidance does not address the procedures that will govern the agency's management and disclosure of information submitted to the agency's Reportable Food Registry, these issues can be addressed in public comments submitted to the agency concerning the draft guidance. In addition, notably, the draft guidance was released only days after the publication of FDA's notice requesting public comment concerning standards and procedures in conjunction with the formation of a new FDA task force to develop recommendations for enhancing the transparency of agency activities.[1] In view of the overall regulatory trend toward increased reporting obligations,[2] transparency, and the potentially adverse implications for responsible companies seeking to manage legal and business risks effectively, food companies may wish to submit comments to FDA urging the agency to adopt clear procedural safeguards before the agency takes action to enforce the Reportable Food Registry requirements.

FDA Draft Guidance on the Reportable Food Registry

General Information and Launch Date

FDA announced the availability of its draft document, "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007" on June 11, 2009.[3] As explained in the draft guidance, the Reportable Food Registry will be implemented as part of FDA's MedWatch^{Plus} Portal, the agency's new electronic system for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. Although the Reportable Food Registry was originally scheduled to launch on September 27, 2008 (one year after the enactment of the FDAAA) and was thereafter delayed until Spring 2009, FDA has now stated that the electronic portal will become operational on the FDA website on September 8, 2009. According to the draft guidance, responsible parties must comply with the Reportable Food Registry requirements beginning on that date.

Who Must Report

The Reportable Food Registry requirements provide that a "responsible party" must use the electronic portal to submit a report to FDA when it determines that an article of food is a "reportable food." A "responsible party" is defined as a person required to submit a food facility registration under section 415 of the Food Drug & Cosmetic Act - *i.e.*, the owner, operator, or agent in charge of a domestic or foreign facility that manufactures, processes, packs, or holds food for consumption in the United States - but not a retailer or a restaurant. In addition, federal, state, and local public health officials may submit instances of reportable food through the portal.

What to Report

A "reportable food" is an article of food, other than infant formula or a dietary supplement product, 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." This definition is generally consistent with the standard that would trigger a Class I recall and would include, for example, foods containing an undeclared allergen. The definition also is comparable to the standard defining "serious adverse events" that triggers mandatory reporting obligations for manufacturers, packers, and distributors of dietary supplements and nonprescription drug products.

FDA has provided a list of certain "data elements" that must be included in an initial report to the agency concerning a "reportable food." These include:

- The food facility registration number of the responsible party making the report
- The date on which the article of food was determined by the responsible party to be a reportable food
- A description of the article of food that the responsible party has determined to be a reportable food, including the quantity or amount
- The extent and nature of the adulteration of the article of reportable food
- When known, the results of any investigation of the cause of adulteration, if it may have originated with the responsible party
- When known, the disposition of the article of food
- The product information typically found on packaging to identify the article of food (*e.g.*, product codes, use-by dates, names of manufacturers, packers, distributors)

The FDA draft guidance specifies that, for each instance of reportable food, FDA intends to assign a unique number allowing for the submission of amended reports and related notifications. The electronic portal also is designed to link multiple reports concerning the same article of food, for example, reports submitted by several responsible parties within the same food chain or additional reports submitted by public health officials.

What FDA May Require After Submission a Report

The FDA draft guidance indicates that, upon receiving a report, FDA may require the responsible party to submit an amended report to provide contact information for the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food, or to notify such parties of certain facts surrounding the report. Such notifications may be made by means of e-mail, fax, text message, first class mail, telephone, or another form of personal contact. Notifications generally must include the same information required in the original report (but not the food facility registration number), the contact information of other parties immediately preceding or following the responsible party in the supply chain and notified by the responsible party, and a description of any actions that the recipient of the notification must perform, as may be specified by FDA. More specifically, FDA may require a recipient of a notification (if the recipient is itself a responsible party) to submit a report to FDA, investigate the cause of the adulteration (if it may have originated with that party), and/or provide further notification to the recipient's immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food.

Other Requirements - Timing and Recordkeeping

A responsible party must submit a report to FDA as soon as practicable, but in no case later than 24 hours after determining that an article of food is reportable. All responsible parties must maintain records related to each report received, notification made, and report submitted to FDA for two years.

Exemptions and Exclusions

Even if a person meets the definition of a "responsible party," the Reportable Food Registry reporting requirements do *not* apply if (1) the adulteration originated with the responsible party; (2) the responsible party detected the adulteration prior to any transfer of the article of food to another person; *and* (3) the responsible party has corrected the adulteration or destroyed the article of food. Notably, the second prong of the exemption states broadly that the article of food must not have been transferred to "another person," rather than specifying that the article of food must not have been transferred to *consumers*. Thus, for example, the exemption does not appear to apply even if an adulteration originating with a responsible party is discovered immediately after transferring the article of food to another facility, the responsible party immediately notifies the third-party facility of the adulteration, and the third-party sends the article of food back to the originating facility or otherwise corrects the adulteration prior to the article of food ever reaching consumers.

In addition, the Reportable Food requirements do not apply to dietary supplements. Dietary supplements, however, are bound by separate serious adverse event reporting requirements prescribed by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. Although the reporting requirements differ somewhat in the details, and the scope of parties responsible for reporting under the Reportable Food Registry is significantly broader, the general criteria for triggering a reporting obligation and the types of information that must be submitted to the FDA are similar.[4] Thus, the implementation of the Reportable Food Registry only expands the type of reporting that already has been required by FDA in other areas.

Issues for Public Comment

Reportable Food Registry Draft Guidance

Although the agency did not specify in its Federal Register notice any particular issues on which it is seeking comments, interested parties may submit comments on the draft guidance for the Reportable Food Registry at any time, and FDA has specifically instructed parties to submit their comments by July 27, 2009 to ensure the agency considers the comments before it begins work on the final version of the guidance.

FDA Transparency Task Force

Regarding the FDA Transparency Task Force, FDA is soliciting comments and input regarding, among other issues, what specific information FDA should provide about agency operations, activities, processes, and decision-making, including enforcement actions, product approvals, and recalls. FDA also has asked what information should remain confidential in order to promote key internal and external policy goals (such as preserving patient privacy) and how FDA should explain the importance of such confidentiality. In addition to submitting comments, businesses also can participate in public meetings to discuss the Transparency Task Force on June 24, 2009 and again in the fall (date TBA). The deadline for submitting written or electronic comments is August 7, 2009.

Kelley Drye & Warren LLP

Kelley Drye's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

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[1] *See* 74 Fed. Reg. 26712 (June 3, 2009) (announcing that the new FDA Transparency Task Force has been convened in response to the memorandum issued by President Obama in January 2009 pledging to take appropriate action, consistent with law and policy, to "disclose information to the public rapidly, and in a form that is easily accessible and user friendly.").

[2] *See*, *e.g.*, FFDCA section 761, requiring manufacturers, packers, and distributors of dietary supplement products to submit to FDA any report of a serious adverse event associated with a dietary supplement used in the United States through the submission of a "MedWatch form" containing prescribed information.

[3] *See* 74 Fed. Reg. 27803.

[4] *Compare* FFDCA section 417 (providing that a person required to submit a registration for a food facility where an article of food is manufactured, processed, packed or held must report to FDA any article of food, other than infant formula, "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 and animals"), *with* FFDCA sections 760 and 761 (requiring manufacturers, packers, and distributors of nonprescription drugs and dietary supplement products to report to FDA any adverse event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or an adverse event that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent such an outcome).