FDA's New Guidance for Industry on Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007

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On March 25, 2010, FDA announced its new guidance for industry entitled, "Guidance for Industry on Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007." 75 Fed. Reg. 14445 (March 25, 2010).

The new FDA guidance provides for the submission of a single report to FDA's Reportable Food Registry by a company when a reportable food is located in more than one of that company's food facilities. The new FDA guidance addresses Reportable Food Registry requirements for companies with multiple food facilities, clarifying procedures that were addressed in previous FDA guidance issued in June 2009 and amended September 2009.

Submitting One Comprehensive Report for All Company Facilities Holding a Reportable Food

Under section 417 the Federal Food, Drug, and Cosmetic Act1 (FDCA), within 24 hours after a "responsible party" for a company determines that an article of food is a "reportable food," the responsible party is required to submit a report to FDA through the electronic portal the agency has established for this purpose. Since the statute defines the "responsible party" to be the person a company has charged with the responsibility of registering a food facility, companies with more than one facility may have more than one "responsible party."

The new FDA guidance makes clear that, in the case that a reportable food report is required for a food that is located in more than one facility of a single company, separate reports need not be submitted by each facility and that, in alternative, it is permissible for a single "combined" report to be submitted which covers all of the company's facilities in which the reportable food is being held. In addition, the guidance specifies that the combined report:

- must include all of the required data elements concerning the reportable food located in each company facility2;
- may be prepared by one authorized individual (e.g., the responsible party for one company facility) who completes the data entry screens presented in FDA's electronic portal by providing the required information for only one of the facilities and attaching the required information

concerning the reportable food located in all other company facilities in a table or spreadsheet[3] format that clearly identifies each facility and the associated reportable food held in the respective facility.

1 The Reportable Food Registry was established under the Food and Drug Administration Amendments Act of 2007, which added new section 417 to the FDCA. FDA began to enforce the new requirement on December 8, 2009. See 21 USC 350f.

2 See "Increasing Transparency and the Reportable Food Registry," Kelley Drye and Warren LLP Client Advisory dated June 23, 2009, for a listing of these required data elements.

3 If using a tabular or spreadsheet format, FDA recommends that responsible parties use the following column headings, in the order listed, for the required (*) and optional information for each facility: Name of facility*, Food facility registration number* , Contact name, Contact phone number, Street address*, City*, State* and Zip code*.