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FDA Announces Effective Date for Reportable Food Registry

On September 8, 2009, the reporting requirements of the Reportable Food Registry (section 417 of the Food Drug and Cosmetic Act) will become effective. Companies registered with the Food and Drug Administration (FDA) should make themselves current on their reporting obligations.

Those companies required to report are called "*responsible parties*" and are those facilities which previously registered under the Act, i.e., facilities engaged in the manufacturing, processing, holding of food for consumption by human, pet or animal in the United States.

A "reportable food" is an article of 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 of humans or animals." The criteria for reporting to the Registry approximate that level of concern comparable to classification of a Class 1 recall. Otherwise "food" includes the standard definition of "(1) articles used for food or drink for man or other animals (other than infant formula), (2) chewing gum, and (3) articles used for components of any such article."

The FDA has issued "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007". Although the Guidance represents FDA's "current thinking", it does not "create or confer any rights" and, "does not operate to bind FDA". The Guidance should be reviewed by all companies who are registered with FDA. (see: 74 Federal Register 27804 (06/11/2009))

The emphasis of the reportable food registry process is on identification and investigation of the potential for more serious health consequences. A report to the Registry is not/shall not be considered an admission that the reported food or incident constitutes adulteration or in any way contributed to any adverse

health consequences, illness or death. In fact, companies may include in their report "a statement, which shall be part of any report that is released for public disclosure, which denies that the report or notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness."

When a responsible party becomes aware of a reportable food, it is to contact FDA within twenty-four (24) hours. A report to the Registry need not be made if the concern or adulteration originates with the responsible party AND the potential adulteration was detected prior to distribution AND the responsible party has corrected the concern. The FDA will then assign a number to the report and will follow up with the responsible party for additional and background information.

Reports are to be filed electronically through the "Reportable Food electronic portal." The initial report should include:

the registration number of the responsible party;

the date the food was determined to be a "reportable food";

quantity of food;

extent and nature of adulteration;

the results of any investigation undertaken by the responsible party to date;

the disposition of the food; and,

the information typically found on the food's packaging, i.e., product codes, use-by date; manufacturer/distributor.

FDA may follow up the initial report with additional questions or requests for additional data and information concerning the product or the incident.

Reports to the Registry must be maintained by the responsible party for a minimum of two (2) years. Calling the FDA District Office or local health official does not relieve a responsible party from its obligation to report to the Registry.

Companies registered with the Food and Drug Administration are encouraged to review the Draft Guidance and to be prepared to comply by the September 8, 2009, deadline.

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