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The FDA's New Reportable Food Registry

Law360, New York (October 07, 2009) -- The U.S Food and Drug Administration recently launched its Reportable Food Registry (RFR) electronic portal. In conjunction with this launch, the FDA has issued a final guidance further discussing the specific requirements.

The RFR requires responsible parties to file a report through the RFR electronic portal at rfr.fda.gov when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are deemed by the FDA to be "reportable foods."

A "responsible party" (defined below) must notify the FDA of a reportable food within 24 hours of its discovery. These new reporting requirements apply to food and animal feed products. Infant formula and dietary supplement products are excluded.

The FDA envisions that the new requirements will assist in faster responses to potential public health risks related to food. Notably, however, although the RFR requirements became effective on Sept. 8, 2009, FDA has announced that it will exercise enforcement discretion until Dec. 8, 2009.

Key RFR definitions and requirements are summarized below.

Reportable Food

A reportable food is an article of food that has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Examples of potential contamination that may trigger the reporting requirement include, without limitation, bacterial contamination, allergen mislabeling or elevated levels of certain chemical components, such as dioxins, benzene, ethyl carbamate, furan and melamine.

Responsible parties must notify the FDA as soon as possible, and no later than within 24 hours of determining that an article of food is a reportable food.

However, a food is not required to be reported if (1) the adulteration originated with the responsible party, (2) the responsible party detected the adulteration prior to any transfer to another person, and (3) the responsible party corrected such adulteration or destroyed the affected food.

Responsible Party

The term "responsible party" refers to any entity that is required to be registered with the FDA as a food establishment (i.e., any facility that manufacture, processes, packs or holds food for sale or consumption (human or animal consumption) in the U.S.).

Federal, state and local governments are also considered responsible parties. However, their reporting requirements are considered voluntarily rather than mandatory.

Once a responsible party believes there is a possible contamination it is required to do the following:

1) Investigate the cause of adulteration if the adulteration of the food originated with the responsible party; and

2) Submit the required data elements in an initial report and to follow-up with supplemental reports on an as-needed basis.

Required data elements include: Food Facility Registration Number, date the article was determined to be a reportable food, description of the food (quantity and amount), extent and nature of the adulteration, results from investigation of the cause of adulteration, disposition of the article of food, and product information typically found on packaging sufficient to identify the article of food.

In addition, a responsible party is required to work with FDA on any follow-up that may be deemed necessary.

The failure to comply with the RFR requirements is a prohibited act under the Federal Food, Drug, and Cosmetic Act, and is punishable by imprisonment of up to one year or a fine of up to $1,000, or both.

Although the RFR entries are not publicly accessible via the FDA Web site, the RFR record is available under the Freedom of Information Act (FOIA). Thus, this informa-

tion will be furnished to third parties making a FOIA request, subject to redaction of proprietary information (including the food facility registration number).

FDA Final Guidance

To further clarify the new reporting requirements, the FDA published a Final Guidance on Sept. 8, 2009, 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 explains the role of responsible parties as outlined above, defines a "reportable food" and expands on other specific questions concerning the RFR.

In this guidance, the FDA announces that although the RFR requirements would be in effect as of Sept. 8, 2009, it would exercise enforcement discretion until Dec. 8, 2009, so as to permit industry an opportunity to implement the necessary protocols for compliance.

A key issue addressed in the guidance is how a responsible party should handle a conflicting test result. That is, where a responsible party initially receives a positive microbiological test result, thus triggering the reporting requirements, but then obtains a negative result after retesting.

Because there are a number of reasons why a food may test positive and then negative, the FDA encourages responsible parties to report in all cases.

As noted above the RFR requirements are not triggered when certain criteria are met, including when the responsible party detects the adulteration prior to any transfer to another person of the affected food.

In the guidance, the FDA further explains that a "transfer" occurs when the responsible person releases the food to a third party. The FDA states that an "intra-company transfer in a vertically integrated company" is not considered a transfer.

Finally, the guidance notes that in addition to the requirements that responsible parties submit a report to the FDA within 24 hours after discovery and to conduct a root-cause analysis, the administration may also require responsible parties to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food.

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