FDA'S REPORTABLE FOOD REGISTRY GUIDANCE FOR INDUSTRY MAY BE ACCESSED AT

http://www.fda.gov/ReportableFoodRegistry

Reportable Food Registry (RFR):

At A Glance

- The RFR was established by section 1005 of the Food and Drug Amendments Act of 2007 (Pub. L.110-085) to provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect the public health.
- The RFR covers all foods regulated by FDA except infant formula and dietary supplements.
- Beginning September 8, 2009, the RFR requires a responsible party to file a report through the RFR electronic portal at ***http://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 "Reportable Foods."
- "Responsible party" is defined as the person who submits the registration information to FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. Federal, state, and local public health officials may also use the portal to report information that may come to them about reportable foods.
- **Responsible parties:**
  - Must report as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food
  - Must submit certain data elements in the initial report
  - Must investigate the cause of the adulteration if the reportable food originated with the responsible party

- May be required to provide notification to immediate previous sources and immediate subsequent recipients of the reportable food after consultation with FDA
- Must provide amended reports as necessary
- Must consult with FDA to follow up as necessary
- Must maintain records related to each report received, notification made, and report submitted to FDA for 2 years

- Failure to report a reportable food is a prohibited act under the Federal Food, Drug, and Cosmetic Act

- A responsible party is not required to report if the adulteration originated with the responsible party; and the responsible party detected the adulteration prior to any transfer to another person of such article of food; and the responsible party corrected such adulteration; or destroyed or caused the destruction of such article of food.

- Data elements that a responsible party may include in initial and follow-up RFR reports to FDA:
  - Food Facility Registration Number
  - Date the article of food was determined to be reportable
  - Description of the food, including quantity and amount
  - Extent and nature of the adulteration
  - Results of investigation of the cause of the adulteration if it may have originated with the responsible party, when known
  - Disposition of the article of food, when known
  - Product information typically found on packaging sufficient to identify the article of food

- A record in the RFR is subject to Freedom of Information Act (FOIA) rules, with appropriate redactions to protect proprietary information and the reporting facility's Food Facility Registration Number.

- RFR submissions will not be viewable by any other submitters.

Contact FDA about the RFR

The **RFR Center** answers questions about Reportable Food Registry policies, procedures and interpretations. Email questions to: *RFRSupport@fda.hhs.gov*

The **RFR Help Desk** for technical and computer-related questions about about the Reportable Food Registry electronic portal Email questions to: *RFRTechSupport@fda.hhs.gov*