Registration Now Available For Compliance With New FDA Regulations

On October 10, the U.S. Food and Drug Administration (FDA) published interim rules in the Federal Register, at 21 CFR Parts 1 and 20 Volume 68 #197, for two of the four parts of legislation that will impact the way business is conducted in the United States. For more information on regulations and the Public Health Security and Bioterrorism Preparedness & Response Act of 2002: www.fda.gov/oc/bioterrorism/bioact.html; interim final rule www.fda.gov/oc/bioterrorism/furls/

In keeping with our commitment to our valued clients, QAI will continue to update you on this matter as information becomes available. Should you have any questions, please contact Ellen P. Holton, QAI Director of Marketing at 858.792.3531 or by e-mail: ellen@qai-inc.com.

Registration Is Now Available

Deadline

Must be registered by December 12, 2003.

Who Must Register

The owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA. There are exceptions. A domestic facility must register whether or not food from the facility enters interstate commerce. A foreign facility must designate a U.S. agent (e.g., a facility's importer or broker) who must live or maintain a place of business in the U.S. and be physically present in the U.S.

Required Information

- Name, address, and phone number for the facility and its parent company (if applicable);
- Name, address, and phone number of the owner, operator, or agent in charge;
- All trade names the facility uses;
- Applicable food product categories;
- A statement certifying the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration;
- A foreign facility must also provide the name, address, and phone number of its U.S. agent;
- All facilities (U.S. and foreign) must provide an emergency contact phone number in the U.S.

How to Register

Facilities can now register online at **www.cfsan.fda.gov/~furls/ovffreg.html,** or contact FDA (877-332-3882, 301-575-0156) to have a registration form sent. FDA encourages online registrations. There is no registration fee.

Prior Notice on Importations

Timeframe

Begins December 12, 2003.

Legislation

The FDA must receive prior notice of food—including dietary supplements and animal feed—imported or offered for import into the U.S. Shipments without adequate prior notice, or from unregistered facilities, will be refused admission and will be held at the entry port unless FDA directs removal to a secure location.

When Must Prior Notice Be Submitted

Prior notice must be received and confirmed electronically by FDA no more than 5 days before arrival and no fewer than:

- 2 hours before arrival by land via road
- 4 hours before arrival by air or by land via rail
- 8 hours before arrival by water
- If arriving by international mail, prior notice must be submitted before the item is sent.
- When an item that is carried by or otherwise accompanies an individual is subject to prior notice, the prior notice must be submitted within the timeframe established for the mode of transportation, listed above, and the food must be accompanied by a copy of the FDA confirmation.

Required Information

The FDA's Fact Sheet and the interim rule at **www.fda.gov/oc/bioterrorism/furls/** list this information. These documents also explain what to do if information changes after you send the prior notice information plus what occurs if you fail to submit adequate prior notice.

How to Submit Information

Prior notice can be submitted electronically either through ABI/ACS or FDA's Prior Notice (PN) System Interface. Beginning December 12, call 800-216-7331 or 301-575-0156 for technical assistance.