Coming Soon: New FDA Requirements

New FDA Food Facility Registration & Recording Keeping Requirements Will Affect the Bottled Water Industry

As a result of the events of Sept. 11, 2001, Congress passed and President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The U.S. Food and Drug Administration (FDA) is responsible for carrying out certain provisions of the Bioterrorism Act including Title III, Subtitle A (Protection of Food Supply). Because bottled water is regulated as a food by the FDA, the bottled water industry will be required to comply with these new regulations. Four provisions in Title III, Subtitle A, of the act require the Secretary of Health and Human Services, through FDA, to propose and issue final food regulations. These four provisions are

- **Section 303**: administrative detention,
- **Section 305**: the registration of food and animal feed facilities,
- **Section 306**: the establishment and maintenance of records, and
- **Section 307**: prior notice of imported food shipments.

While all the sections have impact on the bottled water industry, discussion in this article will be limited to the Registration (Section 305) and Records Maintenance (Section 306) proposed rules. This article includes discussion of the broad industry impact of these regulations as a whole, an overview of key aspects from each rule and a time-table of anticipated important dates.

Industry Impact

Before delving into the details of each of these proposed rules, it is important to put their potential widespread impact into perspective. These regulations apply to anyone who manufactures, processes, packs or holds food for human or animal consumption in the United States whether engaged in interstate or intrastate commerce. In drafting these regulations FDA has chosen to apply the broad definition of "food" from Section 201(F) of the Federal Food Drug and Cosmetic Act. The use of this definition includes food contact substances, ingredients, raw agricultural commodities and alcoholic beverages. Therefore, compliance with these regulations could be required by each facility that manufactures, processes, packs or holds food in addition to each facility that manufactures, process, packs or holds an item used as an ingredient and/or packaging material for a food product. Many industries have submitted comments requesting FDA to clarify and narrow the scope of "facilities" required to comply with these regulations. FDA's decision regarding these comments will not be known until issuance of these final rules, which will occur between October and December of this year.

Registration of Food Facilities

On Jan. 29, 2003, the FDA announced its proposed regulations for the Registration of Food Facilities. The proposed regulation would require domestic and foreign food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the agency between Oct. 12 and Dec. 12, 2003. (The FDA defines facility as any factory, warehouse or establishment of an importer that manufactures, processes, packs, or holds food for human or animal consumption.) Except for specific exemptions, the new regulations would apply to all facilities for all foods and animal feed products regulated by FDA including dietary supplements, infant formula, beverages (including alcoholic beverages) and food additives.

Each facility as defined in the rule would be required to register with FDA either online or via mail and provide the following information.

- The name, full address, phone number, fax number and e-mail address of the facility.
- The name and address of the parent company, if the facility is a subsidiary of the parent company.
- Emergency contact information including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address (if available).
- All trade names the facility uses.
- Product categories as identified in 21 CFR Part 170.3.
- For a foreign facility, the name, address, phone number, fax number (if available) and e-mail address (if available) of its U.S. agent.
- A statement certifying that the information submitted is true and accurate and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available) and fax number (if available) of the person submitting the registration.

Failure to register by Dec. 12, 2003, would result in civil actions and criminal prosecutions. Imported foods from non-registered facilities would be held at port and/or moved to a secure location at the private parties expense.

A few types of facilities are proposed to be exempt from the registration requirement. These include farms, retail food operations, restaurants, nonprofit operations that prepare food for or serve food directly to consumers, fishing vessels not engaged in processing, facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture and some ingredient food processors not shipping directly to the United States.

Final rules are anticipated to be issued by Oct. 12, 2003. These rules are to

2003

October 12, 2003
FDA to have published the final rule for Food Facility Registration.

First date in which FDA is expected to accept registrations from food facilities.

December 12, 2003
Deadline for all food facilities are to be registered with FDA.

FDA to have published the final rule for Establishment and Maintenance of Records.

June 12, 2004
Six month deadline for all facilities not meeting the definition of small or very small businesses are to be in compliance with record keeping regulations.

December 12, 2004
Twelve month deadline for all facilities meeting the definition of small businesses to be in compliance with record keeping regulations.

About the Author
Kristin M. Safran of National Testing Laboratories, Ltd. (NTL) specializes in consulting with bottled water companies regarding testing requirements and bottled water quality. She maintains contact with bottled water regulators, industry associations and the FDA regarding regulatory changes and other issues that impact bottlers. She has authored numerous articles and given various presentations on these topics. Safran can be reached at 800-458-3330 or 440-449-2525 extension 215; food-bev@ntllabs.com

include details on how to register. If FDA should be unable to finalize these regulations, however, food facilities still are required to provide required information to FDA by the Dec. 12, 2003, deadline per the Bioterrorism Act regulations passed by Congress.

Establishment and Maintenance of Records

On May 6, 2003, the FDA announced proposed regulations for the Establishment and Maintenance of Records. The record-keeping proposal is designed to help FDA track foods implicated in future emergencies such as terrorism-related contamination. As proposed, the rules would require facilities that manufacturer, process, pack, distribute, receive, hold or import food destined for consumption in the United States to keep records identifying the immediate source from which they received the food as well as the immediate subsequent recipient to whom they sent it. This regulation requires records to be kept on files for up to two years and would apply to most foreign and domestic food sources and recipients of food destined for consumption in the United States.

A few types of facilities are proposed to be exempt from the registration requirement. These include farms, restaurants, non-profit operations that prepare food for or serve food directly to consumers, fishing vessels not engaged in processing and facilities regulated exclusively by the U.S. Department of Agriculture. The proposed rule would require all businesses—with the exception of small and very small businesses—to comply with the final rule six months from publication. Small businesses (fewer than 500 but more than 10 full-time equivalent employees) would have to comply within 12 months from publication of the final rule. Very small businesses (10 or fewer full-time equivalent employees) would have to comply within 18 months from publication of the final rule. Final rules are expected to be published by Dec. 12, 2003.

Timetable of Important Dates

While subject to change based on final rules and publication dates, the timeline on the previous page provides a rough timeline of the important dates associated with these two rules.

For more information regarding these two rules as well as the other sections of the Bioterrorism Act Title III, Subtitle A go to the FDA website at www.fda.gov/oc/bioterrorism/bioact.html.

Note: If the final rule for the Establishment and Maintenance of Records is published before or after Dec. 12, 2003, the record-keeping deadline dates would need to be adjusted accordingly.

June 12, 2005
Eighteen month deadline for all facilities meeting the definition of very small business to be in compliance with record keeping regulations.

2005

Keeping up with government regulations is a necessity, but it is not always an easy process. Companies must be diligent in this regard or maintain business relationships with reliable sources of regulatory information in order to avoid noncompliance. WQP