

FDA – Interim Final Regulations – Facility Registration & Prior Notice for Food Imports

A copy of the pre-publication draft of the interim final regulations on food facility registration and prior notice for food importation by the Food and Drug Administration (FDA) can be found at the following website:

<http://www.fda.gov/oc/bioterrorism/furls/>

The regulations will be published in the October 10, 2003, Federal Register. The regulations will be effective December 12, 2003, and covered entities must be compliant at that time. However, FDA will continue to take public comment on the implementation of the rules for seventy-five days. FDA has indicated that for the first four months enforcement of the regulations will be primarily on awareness and education, except for potential health hazards.

The Federal Unified Registration and Licensing System (FURLS), which will be used for food facility registration, will become available for use to register food facilities on October 16, 2003, at 6:00 p.m. It can be located through the above website. The owner, operator, or agent-in-charge is required to register all food facilities by December 12, 2003. It requires a person to establish an account (sub-accounts can also be established to allow additional individuals access to the system) and complete the interactive forms. Companies may designate a person or a telephone number as the emergency contact.

The interim final regulations contain a number of significant changes to both the food facility registration rule and the prior notice of food importation regulation. Most notably is the modification in the definition of "food." Food contact material is no longer considered within the definition of "food," but ingredients and additives will continue to be included. Therefore, bottles, caps and seals for bottled water are not included as food products.

FDA and the Bureau of Customs and Border Protection (CBP) have developed a joint system for notice on imports. It will utilize CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS). This system will be available on December 12, 2003. Lot numbers will not be required to be included in bottled water prior notices. Prior notice for food importation must be given 2 hours prior to entry if transported by road, and 8 hours if transported by water.

After IBWA has had an opportunity to research the nuances and applicability to bottled water companies and suppliers, a more in-depth analysis will be provided. In addition, IBWA is providing booth space for FDA to exhibit at

the World Wide Food Expo, as well as conducting a series of seven seminars with the state/regional bottled water associations.

If you have any questions or comments, do not hesitate to contact IBWA.

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