

## *Keeping its Word: FDA Reopens Bioterrorism Act Comment Periods*

### EXECUTIVE SUMMARY

On April 14, 2004, the Food and Drug Administration (“FDA”) announced that it is reopening the comment periods on its interim final rules regarding the registration of food facilities and prior notice of food imports. These two rules implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”). FDA has reopened the comment periods for 30 days. Comments must be submitted by May 14, 2004.

### BACKGROUND

On October 10, 2003, FDA issued interim final rules on food facility registration and prior notification of imports. The rules went into effect on December 12, 2003. The interim final rule on the registration of food facilities requires all domestic and international facilities – unless exempt – that manufacture, process, pack, or hold “food” (including dietary supplements) for consumption in the U.S. to register with FDA. The rule also requires foreign facilities to designate a U.S. agent. The interim final rule on prior notice requires importers to notify FDA before imported food arrives in the U.S.

Because neither FDA nor industry had any experience with how these new rules would work in practice, FDA indicated that it would reopen the comment periods after industry had experience with the new requirements for several

months. FDA has kept its word and has opened a 30-day window to allow the submission of new comments on the rules.

### REGISTRATION OF FOOD FACILITIES: COMMENTS REQUESTED

In the notice, FDA limited the issues on which it is seeking comments to two primary areas that are intended to improve its economic analysis of food facility registration requirements: (1) The cost to foreign facilities of hiring and retaining a U.S. agent; and (2) the effects on small businesses, if any, if some foreign facilities cease exporting to the United States due to the requirement that companies maintain a U.S. agent for registration. The notice provides further details on the specific information that FDA is seeking.

### PRIOR NOTICE OF IMPORTED FOOD: COMMENTS REQUESTED

In the notice, FDA, together with the Bureau of Customs and Border Patrol (“CBP”), announced that it is seeking comments on several issues to assist their analysis of the feasibility of prior notice timeframes as well as alternatives raised by comments. CBP already requires prior notice of imported foods in some circumstances, and FDA and CBP are working to integrate the existing rules with the new rules promulgated under the Bioterrorism Act. To that end, FDA is requesting comments on: (1) Whether food products subject to FDA prior notice requirements

should be eligible for expedited processing and information sharing under CBP rules; (2) if the time frame for land imports is shortened to one hour, whether a faster time frame would be needed for members of the Free and Secure Trade (“FAST”) program; and (3) whether and how the security and verification procedures currently employed by CBP should be modified to handle food and animal shipments regulated by FDA. FDA is also seeking comments on various alternative questions involving time frames, training requirements, and the integrated communication necessary for coordination of prior notice efforts.

#### FOR MORE INFORMATION

Our team continues to monitor FDA and other organizations for additional developments important to our clients. For further information, please call (202) 342-8400 or email:

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