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International Trade Alert

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Do You Import, Manufacture or Distribute Food (Including Dietary Supplements) in the U.S.? FDA's Mandatory Biennial Registration Renewal Period is Now Open for All Domestic and Foreign Food Facilities

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For all foreign and domestic food facility operators and U.S. food importers, now is the time to renew food facility registrations with the U.S. Food and Drug Administration ("FDA") if your food (including dietary supplements) is distributed for consumption in the United States. On October 22, 2012, FDA began accepting biennial registration renewals from food facilities, and will continue to accept the renewals through December 31, 2012. Renewal of the registration during this period is mandatory, even for facilities that are already registered with FDA.

Food Facility Registration Requirements

Section 305 of the Bioterrorism Act, enacted in 2002, amended the Federal Food, Drug and Cosmetic Act (the "FD&C Act" or "the Act") to impose a mandate requiring "any facility engaged in manufacturing, processing, packing, or holding 'food' for consumption in the United States" to register with FDA. The requirement applies to all such facilities, whether in the U.S. or abroad, but excludes foreign facilities whose food products are significantly further manufactured or processed by a subsequent facility prior to export to the United States. Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture's Food Safety and Inspection Service ("FSIS") (*i.e.*, facilities that exclusively process "poultry products," "meat food products," or "egg products" and facilities that slaughter poultry, cattle, sheep, swine, equines, or goats) are also exempt. Pursuant to the Act, the registrations may be submitted by the "owner, operator, or agent in charge of the facility" for domestic or foreign facilities. However, registrations for foreign facilities must also name a U.S. agent for that facility. The failure to timely register a facility constitutes a violation of the Act, and for foreign facilities, as explained below, the Act provides that food from such a facility that is imported, or offered for import into the U.S., is subject to refusal under Section 801 of the FD&C Act.

The FDA Food Safety and Modernization Act ("FSMA"), signed into law by President Obama in January 2011, expanded the registration mandate implemented under the Bioterrorism Act, and introduced three additional significant changes that: (1) required all facilities subject to the registration requirements to submit registration renewals during the period from October through December of each even numbered year; (2) compelled all domestic and foreign facilities' registration to include a statement of their agreement to allow FDA to inspect their facilities; and (3) subjected registered facilities to suspension provisions that authorize FDA to suspend a facility's registration, thereby prohibiting imports or exports of food from the facility into the U.S. and prohibiting the introduction of food from the facility into interstate or intrastate commerce in the U.S., upon a determination that the facility created or had reason to know that food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Enhanced Registration Requirements

In addition to mandating inspection assurance statements from food facilities, the FSMA also expanded the scope of the mandatory registration information by adding a requirement that food facilities provide an e-mail address for the contact person for a domestic facility, or for the U.S. agent of a foreign facility, as well as information regarding other applicable food categories, as determined appropriate by FDA, for foods manufactured/processed, packed, or held at registering facilities.

On October 20, 2012, FDA released binding guidance to announce that it had made such a determination, as authorized under the FSMA, and that all future food facility registrations and registration renewals shall include information regarding an expanded list of food categories, in addition to the food categories already identified in FDA's regulations, at 21 C.F.R. § 170.3. The expanded food

categories are set forth in the FDA notice, available on its website. *See* FDA, **Food Defense: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (October 2012) at 5-7**.

Import Detention Regulations and Customs Implications

The Government may also bar importation of food items from foreign food facilities that have not filed a valid registration with FDA. Under FDA's regulations implementing the Bioterrorism Act of 2002, any foods imported from a foreign facility that has failed to timely register may be detained at the port of entry until proper registration information is provided. In the event of detention, any costs incurred may be borne by the purchaser, owner, importer, or consignee. The detention period, which may not exceed thirty days, is intended to give FDA time to seek an injunction or initiate a seizure action against the food, as warranted. No transfers of the detained imports can be made until FDA releases the shipment or the detention period expires. *See* 21 C.F.R. § 1.285 (outlining the process and procedure regarding holds placed by FDA on food imported from unregistered facilities).

Fee Policy

Lastly, although FDA does not require a registration fee, or an initial inspection fee, the FSMA authorizes the FDA to assess and collect fees related to reinspections of domestic and foreign food facilities, and importer reinspections. The fees are intended to cover FDA's costs for conducting further inspections as necessary when an initial inspection has identified certain food safety problems. FDA will invoice the domestic facility reinspected or, in the event of reinspection of a foreign facility, its U.S. agent, for the direct hours, including travel, spent to perform the reinspection. The fee rates for fiscal year 2013 recently took effect on October 1, 2012, and will be an hourly rate of $221 per hour if no foreign travel is required, or $289 per hour if foreign travel is required. FDA is currently developing a guidance document regarding the process to request a fee reduction. Significantly for importers, although FDA will continue to conduct follow-up inspections of food offered for import that fails to meet the standards of the FD&C Act, FDA is not assessing fees against importers for the reinspections at this time.

What Does this Mean for Your Company?

- ***All domestic and foreign food facilities should update their FDA registration before December 31, 2012 to avoid potential criminal liability and U.S. import disruptions.*** The FDA is accepting registrations and registration renewals online or in paper form through submission of a Form 3537 via fax or mail. For companies with multiple food facilities, the FDA is also accepting submissions on CD-ROM by mail. To submit a registration or registration renewal online, **visit the FDA Industry Systems, by clicking here**. If your company is already registered, find your account identification and password information, or in the alternative, file a new registration. For submission via standard mail or fax, **the application form (Form 3537) can be found by clicking here**. In completing the registration, it is important to review the newly-expanded food categories to ensure that the registration properly reflects all required information regarding each food facility's activities.
- ***All foreign food facilities and U.S. agents for foreign food facilities should review the new user fee policy and if necessary, clarify or revise their agency relationship.*** It is important to ensure that entities acting as U.S. agents for foreign food facilities understand their duties as an agent, and are prepared to fulfill those duties. The U.S. agent acts as a communication link between FDA and the facility, and the FDA considers providing information to the U.S. agent the same as providing information directly to the foreign facility. Further, as noted, the U.S. agent will be billed for any foreign facility reinspections conducted by FDA. Therefore, a foreign facility should carefully vet any U.S entity it is considering designating as its U.S. agent, and may opt to designate a company with whom it has an existing relationship. Additionally, U.S. entities, such as customers or brokers, who have agreed to serve as the U.S. agent for a foreign facility, should review the terms of their agreements to confirm that they feel comfortable prior to accepting this role.
- ***Facilities should review and update their FDA compliance programs.*** Companies should anticipate an increased number of FDA facility inspections, particularly in foreign facilities. To prepare for an inspection, domestic and foreign food facilities that are subject to the FDA registration requirements should review and update their standard operating procedures and compliance documents as needed to meet the FD&C Act requirements. Additionally, each facility's compliance program should incorporate procedures for verifying that the facility's FDA registration is updated within 60 calendar days of any change in the required registration information.

Contact the attorneys in Venable's **International Trade and Customs Group** or **Dietary Supplements, Cosmetics and Functional Foods Group** for additional details on how the FDA

Registration and Registration Renewal requirements may impact your company, as well as due diligence steps to consider prior to engaging in import or export of food and food products to the U.S.