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MEMORANDUM

October 9, 2003

BY ELECTRONIC MAIL

FROM: Olsson, Frank and Weeda, P.C.

RE: Registration of Food Facilities -- FDA Interim Final Rule

The Food and Drug Administration (FDA) has issued its interim final rule requiring that facilities that manufacture/process, pack, or hold food intended for human or animal consumption in the United States must register with FDA, unless exempt. The rule is expected to publish in the Federal Register on October 10, 2003. The rule in a [prepublished format](#) is available from the FDA website and at the following link:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/cf0354.pdf>

The interim final rule, together with the [prior notice of imported food shipments](#) (*see* our accompanying memorandum and <http://www.fda.gov/OHRMS/DOCKETS/98fr/cf0356.pdf>), are the first two of four rules implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The Bioterrorism Act was passed in response to the events of September 11, 2001, and Title III of the Bioterrorism Act includes provisions designed to protect the U.S. food supply from acts of bioterrorism or intentional contamination.

This memorandum briefly summarizes the registration interim final rule. A more detailed memorandum will follow shortly.

The registration interim final rule will affect most U.S. and foreign entities that manufacture, process, pack, or hold food products for the U.S. market. The registration requirement applies to covered *facilities*, not companies. A single company may be required to register multiple facilities. "Food" is defined very broadly in the regulations to cover all human and animal food regulated by FDA, including food ingredients, dietary supplements, fresh produce, fish and seafood, alcoholic

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beverages, live animals to be processed into food, animal feed, and pet food. It does not include food contact substances, such as food packaging, that are not intended to have any technical effect in the food.

The registration final rule differs in several respects from the proposed rule issued by FDA in February. 68 Fed. Reg. 5378 (Feb. 3, 2003). For example, food contact substances have been removed from the definition of "food." Therefore, facilities that manufacture/process, pack, or hold food contact substances are not required to register. The requirements for updating registration information in the event such information changes also have been relaxed. Registrants are required to update mandatory registration information only; they are not required to update optional information. The deadline for submitting updates has been extended from 30 days to 60 days after the change.

The registration interim final rule is effective beginning December 12, 2003. All food facilities required to register with FDA must do so by that date. However, FDA is accepting comments from interested persons for the next 75 days. In March 2004, the agency will reopen the comment period on the regulations for an additional 30 days and then issue final regulations. During this time, FDA intends to emphasize educating industry about the new requirements. FDA is not expected to begin strictly enforcing the registration regulations until after it has issued final regulations.

Summary of the Facility Registration Interim Final Regulations

The key features of the registration interim final regulations are:

- Any domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the United States is required to register the facility with the FDA by **December 12, 2003**, unless the facility is exempt.
- Facilities exempt from registration include:
 - Farms.
 - Retail food establishments that sell food directly to consumers as their primary function (*i.e.*, if the establishment's annual monetary values of sales of food directly to consumers exceeds its annual monetary value of sales of food to other buyers).
 - Restaurants.
 - Transport vehicles that hold food only in the usual course of business as carriers.
 - Fishing vessels not engaged in processing.

- Facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture.
- Foreign facilities if food from such facilities undergoes further manufacturing/processing or packaging (of more than a *de minimis* nature) at another foreign facility before it is exported to the U.S. This means that the last foreign facility that manufactures/processes or packages the food, and any subsequent foreign facility that packs or holds the food, must register.
- Foreign facilities that are required to register must also designate a “U.S. agent.” A “U.S. agent” must live or maintain a place of business in the United States and be physically present in the United States.
- The owner, operator, or agent in charge of a covered facility (or an individual authorized by such person) is responsible for submitting the registration to FDA.
- Covered facilities will have until December 12, 2003 to register by completing Form FDA 3537. Facilities can register by logging on to www.fda.gov/furl beginning October 16, 2003, by mailing or faxing the completed form to FDA, or by sending a CD-ROM with the required information to FDA. A facility registering via the Internet will receive a confirmation and registration number “instantaneously.” Receipt of a registration number will take longer if a facility registers by mail or CD-ROM.
- The following information is required to be provided in the registration:
 - The name, address, and phone number of the food facility.
 - The name, address, and phone number of the parent company, if the facility is a subsidiary.
 - The name, address, and phone number of the owner, operator, or agent in charge.
 - For foreign facilities, the name, address, phone number, and emergency contact number of the “U.S. agent.”
 - For domestic facilities, an emergency contact phone number.
 - All trade names used by the facility. (A “trade name” is defined as “the name or names under which the facility conducts business, or additional names by which the facility is known.” A trade name is associated with a facility, whereas a brand name is associated with a product.)

- The categories of food products manufactured/processed, packed, or held at the facility as identified in FDA's regulation, 21 C.F.R. § 170.3.
- A certification that that the information submitted is true and accurate.
- The name of the individual submitting the registration (and, for registrations by paper or CD-ROM, that individual's signature).
- FDA encourages submission of certain additional optional information in registrations.
- If any of the required information listed above changes, the registrant must submit an updated Form 3537 to FDA within 60 days of the change.
- If a facility goes out of business, the registrant must submit a cancellation using Form FDA 3537a to FDA within 60 days.
- If a facility is required to register, it is a violation of United States federal law to fail to register. If a foreign facility required to register fails to do so and food from that facility is offered for import into the U.S., the Bioterrorism Act requires that the food be held at the port of entry.
- Facilities will be able to register beginning on October 16, 2003.

A detailed memorandum describing the interim final rule will be available shortly. If you have any questions, please contact Bob Hahn at 202-789-1212 or rhahn@ofwlaw.com.

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