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MEMORANDUM

May 25, 2010

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BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: The Reportable Food Registry – FDA Issues Draft Revised Guidance and Request for Comments, and Launches New Electronic Portal

The Food and Drug Administration (FDA) has issued a draft revised guidance document on the Reportable Food Registry. FDA, *Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007* (edition 2) (available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm212793.htm>). Although comments may be submitted at any time, to be considered in preparation of the final guidance, comments must be submitted by **July 26, 2010**.

FDA is also requesting comments on the Reportable Food Registry, specifically on the meaning of the word “transfer.” 75 Fed. Reg. 29350 (May 25, 2010).

Effective immediately, a new electronic portal must be used to submit reports to the Reportable Food Registry: www.safetyreporting.hhs.gov. This new Safety Reporting Portal is a joint FDA-National Institutes of Health (NIH) system that will be used for reporting of several categories of safety information to FDA and NIH, including safety information related to reportable foods, pet foods, and animal drugs. The previous reporting portal on FDA’s website will redirect the viewer to the new portal.

Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA) added a new section 417 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring FDA to

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establish a Reportable Food Registry. Under the FDAAA, a responsible party¹ must submit a report to FDA within 24 hours after the responsible party determines that any food it has manufactured, processed, packed, or held is a reportable food.² FDA is required to promptly review the information submitted by the responsible party and, if the food is a true reportable food, enter the information in the Reportable Food Registry. FDA may direct the responsible party to notify the immediate previous source and/or the immediate subsequent recipient of the reportable food. The purpose of the Reportable Food Registry is to provide a “reliable mechanism to track patterns of adulteration in food” which FDA can use to target its limited inspection resources.

This reporting requirement became effective on September 8, 2009. At that time, FDA issued a guidance document explaining implementation of the Reportable Food Registry (*see* our memorandum dated Sept. 9, 2009). Even after issuance of the guidance, many questions about the new requirement remained (*see* our memorandum dated Oct. 9, 2009).

Draft Revised Guidance

FDA’s revised guidance includes the following changes and additions:

- The New Electronic Portal
 - As of May 24, 2010, the Reportable Food electronic portal will be a part of the FDA-NIH Safety Reporting Portal.³
 - FDA anticipates this to be the final version of the portal, though there may be minor adjustments and system enhancements.

¹ A “responsible party” is defined as a person who submits the FDA registration (required under FD&C Act section 415) for the food facility at which the reportable food was manufactured, processed, packed, or held.

² A “reportable food” is defined as an article of food (other than a dietary supplement or infant formula) “for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences of death to humans or animals.” The definition includes animal feed and pet food. It does not include foods regulated exclusively by the U.S. Department of Agriculture. Serious adverse events involving dietary supplements and infant formula are subject to separate reporting requirements.

³ The new electronic portal, www.safetyreporting.hhs.gov, will eventually provide “one-stop shopping” for reporting safety problems involving a wide range of products regulated by an array of federal agencies. For now, it offers the following reporting: (1) reports by industry to the Reportable Food Registry for safety problems with food, including animal feed; (2) reports by pet owners and veterinarians for safety problems with pet foods and pet treats; (3) reports by manufacturers of adverse events associated with animal drugs; and (4) reports by biomedical researchers of adverse events associated with human gene transfer clinical trials.

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- The portal can be accessed in either of two ways: (1) by clicking on “Report a Problem” on the FDA website home page (www.fda.gov); or (2) by entering the following URL into your browser: www.safetyreporting.hhs.gov and selecting “Reportable Food Report.”
- When accessing the portal, you will be asked if you want to create an account or to submit a report as a guest. By creating an account, you will be able to see a list of reports you have already submitted, and to save a report and finish it at a later time. In addition, once an account is created, the system automatically pre-populates subsequent reports with the information it possesses.
- Completing/Submitting the report
 - Required data elements are clearly indicated by asterisks.
 - If you attach documents to the report, FDA recommends that they be in the English language if possible (except for name of individuals, companies, streets, and trade names). If any material is in a foreign language, FDA recommends that an accurate and complete English translation be included.
 - FDA will issue a confirmation with a unique number for each submission, whether an initial report or an amended report. For submitters that have a portal account, the unique number consists of the Individual Case Survey Report ID (ICSR) number. For guest users of the portal, the unique number has two parts: the ICSR number and the 16-digit Report Identification Key.
 - To amend a report:
 - An account holder should log into his/her account, choose the report to be amended from a list of submitted reports, edit the report (after the most recent version of the report loads), and click “submit.”
 - A guest user should enter as a guest again, select the option “Follow-up on a report previously submitted as a guest portal user,” enter the 16-digit Report Identification Key received upon submitting the initial report, edit the report (after the most recent version of the report loads), and click “submit.”
- Clarification of particular situations
 - **Allergens.** A human food that contains an undeclared “major food allergen” (*i.e.*, peanuts, tree nuts, milk, eggs, wheat, soybeans, fish, crustacean shellfish, or protein derived from any of these foods) may be a reportable food, regardless of how the major food allergen was incorporated into the human food. NB: We

interpret this to mean that such a food is likely to be considered a reportable food even if the presence of the major food allergen is unintentional.

- **Food for Export.** If a food facility manufactures food for consumption in the United States and food for export, the facility is required to submit a report if it determines that a food intended only for export is a reportable food. If a facility is a responsible party and the facility determines that a food it has manufactured, processed, packed, or held is a reportable food, it must submit a report, even if the reportable food is solely for export.
- **Foreign Facilities Shipping to a Location Not in the United States.** A foreign food facility that is registered with FDA and therefore is a responsible party is not required to submit a report if it determines that a food shipped elsewhere (*i.e.*, not to the United States) is a reportable food. However, FDA encourages the foreign facility to notify the recipient of the food and take appropriate action.
- **Effect of Government Reporting.** A responsible party's obligation to report a reportable food is not altered by the fact that a federal, state, local, or foreign public health official has submitted a report about the same article of food.
- **Field Testing of Produce.** If a food facility contracts with a farm to buy its produce, and the facility tests the produce in the field before harvest and determines it is a reportable food, the food facility is not required to submit a report. Because the produce is still on the farm, the food facility did not manufacture, process, pack, or hold the reportable food, and therefore never became a responsible party with respect to that food. (The result would be different if the contaminated produce had been shipped to the food facility.) Provided the farm is not required to register with FDA under FD&C Act § 415, it also is not a responsible party and is not required to submit a report.
- **Effect of Notification.** If a food facility receives allegations of product problems from a consumer, restaurant, or other source, it should investigate the allegations to determine whether the food is a reportable food. However, if a food facility receives a notification under FD&C Act § 417(d)(7) about a reportable food (*e.g.*, from its supplier or customer), and the food facility meets the definition of "responsible party" with respect to that article of food, it is required to submit a report to the Reportable Food Registry. FDA considers a food facility to have received a notification if a responsible party that has previously filed a reportable food report contacts the facility and provides it with an FDA-issued ICSR number for linkage to the previous report. If the notification does not include the ICSR number and the facility is unable to contact that party to obtain the number, the facility should still submit a report and should enter up to eleven zeroes (*i.e.*,

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“00000000000”) in response to the question “What is the FDA-issued ICSR number for this Reportable Food provided by the site that notified you?”

- **Dropped Bulk Shipments.** If a food facility receives a bulk trailer shipment of ingredients from a supplier, the trailer is left on the property of the food facility, and the food facility tests the food and rejects the shipment because it determines the shipment is a reportable food, the food facility is required to submit a report. According to FDA, even though the food facility did not take ownership of the food and returned it to the supplier, it is deemed to have held the food at its facility, because the trailer was no longer in transit after it was left on the food facility’s property. Therefore, the food facility is a responsible party with respect to that food.
- **Same Implicated Food at Multiple Facilities.** If a company determines that a reportable food is held at more than one of its facilities (*e.g.*, multiple distribution centers), it may submit a combined report for that reportable food. The owner, operator, or agent in charge of each facility may authorize an individual to submit a combined report for all of the facilities. The fields in the Reportable Food electronic portal should be completed with the information for one of the facilities, and the required information for the other facilities should be provided in a separate attachment in tabular or spreadsheet format, using the following headings: name of facility; food facility registration number; contact name; contact phone number; and street address, city, state, and zip code.⁴

Request for Comments on “Transfer”

Under FD&C Act § 417(d)(2)(B), a responsible party is *not* required to submit a report to the Reportable Food Registry when *all* of the following criteria are met:

- The adulteration originated with the responsible party;
- The responsible party detected the adulteration prior to any transfer of the reportable food to another person; and
- The responsible party either corrected the adulteration or destroyed or caused the destruction of the reportable food.

⁴ This guidance reaffirms FDA’s previously issued guidance document. *Guidance for Industry: Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007* (see our memorandum dated March 24, 2010).

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For purposes of this exception, a transfer occurs when the responsible party releases the food to another person.

FDA is seeking comments on whether this interpretation of the term “transfer” is appropriate, and, if not, what other interpretations would be more appropriate. Specifically, FDA is requesting comments on whether the existence of a “transfer” should be dependent upon possession of the food, ownership of the food, or whether other possible interpretations (*e.g.*, a combination of possession and ownership) should be considered.⁵

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We trust this information is useful. If you have any questions, please contact Bob Hahn at (202) 518-6388, or rhahn@ofwlaw.com.

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⁵ For example, if a food facility leases a warehouse or part of a warehouse and ships a reportable food to that leased warehouse, has a transfer occurred? If FDA determines that a transfer has not occurred (because the food facility retains control of food shipped to the leased warehouse), then the food facility would not be required to submit a report if it determines that an article of food shipped to the leased warehouse is a reportable food, provided the adulteration originated with the food facility, and the food facility destroys the food or corrects the adulteration.