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MEMORANDUM

March 23, 2010

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BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: GAO Reports Criticize FDA's Handling of GRAS Food Ingredients and Food Irradiation Petitions

The U.S. Government Accountability Office (GAO) recently published two reports containing recommendations for improvement of food regulatory activities by the Food and Drug Administration (FDA):

- Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS) (available at <http://www.gao.gov/new.items/d10246.pdf>) ; and
- Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions (available at <http://www.gao.gov/new.items/d10309r.pdf>).

With regard to FDA's regulatory activities concerning food ingredients determined to be GRAS, the GAO recommended that to better ensure FDA's oversight of the safety of GRAS substances, the agency should develop strategies to:

- Require any company that conducts a GRAS determination to provide FDA with basic information -- as defined by the agency to allow for adequate oversight -- about the company's determination, such as the substance's identity and intended uses, and to incorporate such information into relevant agency databases and its public website;
- Minimize the potential for conflicts of interest in companies' GRAS determinations, including taking steps such as issuing guidance for companies on conflict of interest and requiring information in GRAS notices regarding expert panelists' independence;

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- Monitor the appropriateness of companies' GRAS determinations through random audits or some other means, including issuing guidance on how to document GRAS determinations;
- Finalize the rule that governs the voluntary GRAS notification program, including taking into account the experience of the program to date, incorporating input from a new public comment period, and reporting to Congress and the public the agency's timeline for making it final;
- Conduct reconsiderations of the safety of GRAS substances in a more systematic manner, including taking steps such as allocating sufficient resources to respond to Citizen Petitions in a timely manner, developing criteria for the circumstances under which the agency will reconsider the safety of a GRAS substance, and considering how to collect information from companies on their reconsiderations; and
- Help ensure the safety of engineered nanomaterials that companies market as GRAS substances without the agency's knowledge, including taking steps such as issuing guidance recommended by the agency's nanotechnology taskforce, developing an agency definition of engineered nanomaterials, and requiring companies to inform FDA if their GRAS determinations involve engineered nanomaterials.

With regard to FDA's regulatory activities concerning food irradiation petitions, the GAO recommended that to more effectively manage such petitions, and to be consistent with FDA regulations, the Office of Food Additive Safety should:

- Document its key decisions in its administrative files; and
- Communicate its key decisions to petitioners and, for new petitions, the status of FDA decisionmaking, consistent with regulatory timeframes.

Additional information about the GAO reports is available at its website, <http://www.gao.gov>.

If you have any questions about FDA regulatory activities with respect to GRAS food ingredients or food irradiation petitions, or about the GAO reports, please contact Michael O'Flaherty at 202/518-6320 or moflaherty@ofwlaw.com.

MJO:jsj