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ALERTS

Food, Drug & Device Law Alert - FDA Extends Comment Periods For Food-Related Rules And Guidance

November 25, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently announced that it is extending the comment period for two proposed final rules that are part of the implementation of the Food Safety Modernization Act (FSMA). The comment period for the proposed rules on the "Foreign Supplier Verification Program" and "Accreditation of Third Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" was extended from Nov. 26, 2013 to Jan. 27, 2014.

As noted in the prior Alert here, in general the Foreign Supplier Verification Program includes several elements designed to ensure that food produced overseas complies with the same safety standards as food produced domestically:

- **Compliance Status Review**: Importers would have to review the compliance status of the food and the foreign supplier (e.g., registration, warning letters) before importing the food and periodically thereafter.
- **Hazard Analysis**: Importers would have to analyze the hazards associated with each food they import. The hazard analysis would identify the hazards that are reasonably likely to occur for each type of food imported, and evaluate the severity of the illness or injury if such a hazard were to occur.
- **Verification Activities**: Importers would have to conduct activities that provide adequate assurances that the hazards identified as reasonably likely to occur are adequately controlled. Verification activities could include: onsite auditing of foreign suppliers; periodic or lot-by-lot sampling and testing of food; and periodic review of foreign supplier food safety records; or other appropriate risk-based procedures.
- **Corrective Actions**: Importers would have to review complaints they receive concerning the foods they import, investigate the cause or causes of adulteration or misbranding in some circumstances, take appropriate corrective actions, and revise their FSVPs when they appear to be inadequate.
- **Periodic Reassessment of the FSVP**: Importers would have to reassess their FSVPs within three years of establishing the FSVP or within three years of the last assessment. However, importers would have to reassess the effectiveness of their FSVP sooner if they become aware of new information about potential hazards associated with the food.

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- **Importer Identification**: Importers would be required to obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number for their company and to ensure that, for each food product offered for importation into the United States, their name and DUNS number are provided electronically when filing for entry with Customs and Border Protection.

- **Recordkeeping**: Importers would have to keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

The Accreditation of Third Party Auditors rule sets eligibility requirements for recognition as an accreditation body, as noted in this prior Alert. Further, the proposed rule would require accreditation bodies to:

- assess third-party auditors for accreditation;
- monitor performance of the third-party auditors it accredits and notify the FDA of any change in, or denial of, accreditation;
- assess and correct any problems in its own performance;
- submit reports and other notifications to the FDA;
- protect against conflicts of interest; and,
- maintain and provide the FDA access to records.

FDA stated that it extended the comment period for these rules to allow interested parties to consider the interrelationship between these two proposed rules and the proposed rule announced in October 2013, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals."

Separately, FDA also recently announced that it has extended the period to submit comments on the draft guidance titled, "Frequently Asked Questions About Medical Foods: Second Edition" until Dec. 16, 2013. Generally speaking, medical foods are those formulated for the dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation and are intended to be consumed or administered under the supervision of a physician. Medical foods are specifically formulated for patients who have a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary food or certain nutrients, or who have other special medically determined nutrient requirements that cannot be met by modification of a normal diet alone.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys:

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