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ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule On CGMPs For Food To Implement Parts Of Food Safety Modernization Act

January 11, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

On the two year anniversary of the adoption of the Food Safety Modernization Act (FSMA or Act), the FDA recently issued a lengthy proposed rule to update its existing rules on current Good Manufacturing Practices for food. At the same time, the FDA issued a separate proposed rule covering standards for produce safety (which is the subject of a contemporaneous Alert) and stated that it expects to release soon rules on foreign supplier verification required by the FSMA.

The proposed update to current Good Manufacturing Practices for foods will apply generally to any food facility that is required to register with the FDA. The rule does propose clarifications to the definition of “facility” and the exemption for “farms” to require compliance with the proposed rule by farms that conduct activities that require registration, such as on-farm manufacturing or processing of food not consumed on the farm.

Perhaps the highlight of the proposed rule is a proposed new Part 117, Subpart C, to 21 C.F.R. adopting requirements for hazard analysis and risk-based preventive controls. Some of the key components of these requirements include:

- A written hazard analysis identifying and evaluating known or reasonably foreseeable for each type of food manufactured, process, packed or held in the facility
- Written and implemented preventive controls, including process, food allergen, and sanitation controls, to assure that any hazards that are reasonably likely to occur are prevented or at least significantly minimized so that food at the facility will not be adulterated
- A written recall plan covering at least foods with hazards that are reasonably likely to occur
- Monitoring the preventive controls to provide assurance that they are consistently performed, and documenting the implementation of the monitoring procedures
- Written corrective actions to be taken in case the preventive controls are not performed or in the event of an unanticipated problem
- Verification activities, including validation of at least a subset of the preventive controls, verification that the preventive controls are consistently implemented and effective, and verification of appropriate decisions on corrective actions

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- A re-analysis of the food safety plan at least every three years
- A "qualified individual" – by experience or completing a standard curriculum – must oversee all of the above activities
- Records for all of the above activities, including the training of the qualified individual

The proposed rule includes revisions to 21 C.F.R. Part 110 on Good Manufacturing Practices for food, including provisions to clarify that protection against contamination requires protection against cross-contact of foods to address allergens and to extend contamination protection to food packaging materials. This portion also deletes certain recommendations, including those directed to specific temperatures for maintaining frozen, refrigerated, or hot foods. The content is re-located to Part 117, Subpart B.

Proposed Part 117, Subpart D, addresses the requirements for a "qualified facility" and requirements to submit various types of documents to FDA to establish such status.

Proposed Part 117, Subpart E, establishes the conditions and procedures for withdrawing an exemption given to a qualified facility.

Proposed Part 117, Subpart F, includes records requirements related to the other sections of Part 117, including retention requirements.

The proposed rule also includes several exemptions. The FDA provided a 120 day period for the public to comment on the rule, and will publish a final version at some point thereafter. Although the rule will be effective 60 days after the FDA adopts the final version, the FDA will generally give businesses one year from the publication of the final rule to comply, small businesses two years, and very small businesses three years.

A copy of the FDA's proposed rule on cGMPs for food can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.