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ALERTS

Food, Drug And Device Law Alert - New Guidance Details FDA's Intent To Use Discretion For Enforcing Portions Of Food Safety Modernization Act

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Earlier this month, the Food and Drug Administration (FDA) issued a guidance, "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs," announcing that it intends to exercise enforcement discretion for certain provisions in four of the seven major Food Safety Modernization Act (FSMA) rules. This means that during the enforcement discretion period, the FDA does not intend to enforce these provisions as they currently apply to certain entities or activities.

The enforcement discretion pertains to specific provisions in the following rules:

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Foreign Supplier Verification Programs (FSVP)
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

The enforcement discretion relates to:

- facilities that would be farms except for certain factors and activities
- written assurances provisions in all four rules related to the control of identified hazards or microorganisms that are a potential risk to public health
- the animal food preventive controls requirements for certain manufacturing/processing activities performed on human food by-products used as animal food
- FSVP requirements for importers of food contact substances

According to the announcement, the FDA had previously extended the compliance dates for many of the provisions covered by this enforcement discretion guidance (see August 2016 compliance date extension) but is now exercising enforcement discretion.

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The agency stated that issuing this enforcement discretion guidance is consistent with other actions it has taken to ensure the FSMA rules are as effective as possible while providing flexibility where necessary and appropriate support compliance. These enforcement discretion policies will be in place until the FDA takes further action on each of these issues.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug and Device group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.