

ALERTS

Food, Drug & Device Law Alert - FDA Issues Final Rule On Criteria For Administrative Detention Of Food

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Earlier this month, the Food and Drug Administration (FDA) issued a final regulation on the criteria for ordering the administrative detention of food, implementing Section 207 of the Food Safety Modernization Act (FSMA). FSMA lowered the standard for the FDA to order the administrative detention of food to whether FDA has “reason to believe” that the food is adulterated or misbranded. Before FSMA, FDA could only detain a food product when it had credible evidence that the food product presented a threat of serious adverse health consequences or death to humans or animals.

Consistent with FSMA, the final rule amends 21 C.F.R. § 1.378 to adopt the “reason to believe” standard. Similarly, 21 C.F.R. § 1.393 now states that FDA must issue the detention order in writing, in the form of a detention notice, when an officer or authorized employee has reason to believe the food is adulterated or misbranded. Under the rule, FDA can detain suspect food for a maximum of 30 days while it determines whether to take further enforcement action, such as seizure. If FDA does not issue a written order terminating the detention within 30 days, the detention terminates automatically after the 30 days pursuant to 21 C.F.R. § 1.384.

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.

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