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## MEMORANDUM

**From:** Elizabeth Barr Fawell  
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**Date:** July 16, 2020

**Re: FDA Announces Inspections of Small Businesses under FSMA Intentional Adulteration Rule to Begin March 2021**

The U.S. Food and Drug Administration (FDA) recently announced that routine inspections of small businesses to verify compliance with the FDA Food Safety Modernization Act's (FSMA) Intentional Adulteration (IA) rule will begin in March 2021.<sup>1</sup> The IA rule requires food facilities covered by the rule to develop and implement a food defense plan that identifies significant vulnerabilities at actionable process steps and implements mitigation strategies to address those vulnerabilities.

Although the compliance date for the IA rule for small businesses (*i.e.*, those with fewer than 500 employees) is July 27, 2020, FDA postponed most routine inspections due to COVID-19, and has only recently announced its plans for continuing domestic inspections beginning the week of July 20, 2020.<sup>2</sup> Among the inspections that were temporarily postponed by FDA were those of large businesses under the IA rule, which, following a compliance date of July 2019, were due to begin in March 2020. FDA postponed IA inspections of large businesses to provide additional time for industry to benefit from certain guidance, training and other tools that FDA issued last year. Recognizing the unique situation COVID-19 has created, FDA believes that postponing inspections of small business until March 2021 similarly will help facilitate industry's continuing efforts to put in place measures that will protect public health while allowing the FDA additional time to conduct outreach to stakeholders

In an updated conversation<sup>3</sup> with Ryan Newkirk, Senior Advisor for Intentional Adulteration with the Food Defense and Emergency Coordination Staff, and Captain Jon Woody, Director, Food Defense and Emergency Coordination Staff, about the implementation of IA rule, Mr. Newkirk explains that FDA's focus during these inspections will be to "educate while we regulate." Initial routine

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<sup>1</sup> FDA Constituent Update, Inspections of Small Businesses under the FSMA Intentional Adulteration Rule to Begin March 2021, (July 15, 2020), <https://bit.ly/30hMTPO>.

<sup>2</sup> See HL Memo – COVID-19 Update: FDA Prepares to Resume Domestic Inspections, (July 12, 2020), <https://bit.ly/2B2BkUf>.

<sup>3</sup> FDA, Protecting the Food Supply from Intentional Adulteration, such as Acts of Terrorism, (July 15, 2021), <https://bit.ly/3j5roKB>.

inspections under the IA rule will consist of food defense plan “quick checks” to certify that the facility has satisfied the basic requirements of the rule. FDA investigators will ask the owner or operator of the facility a series of questions such as “do you have a food defense plan?” and may provide educational materials.

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We will continue to monitor developments related to FDA’s implementation of the IA rule and plans for IA inspections. If you have any questions on this or any other matter, please do not hesitate to contact us.