

MEMORANDUM

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Re: FDA Publishes List of All General FDA Form 483 Inspection Citations for Every Food Facility Since 2008

The Food and Drug Administration (FDA) has released an Excel file that lists all general inspection citations included on every FDA Form 483 (Inspectional Observations) issued for almost the past ten years, from October 2008 through February 2018. ^{1/} The information is specific to each establishment that has been inspected by FDA across all areas of the agency's jurisdiction, including food facilities. We encourage all food companies to review their data so that they are aware of the information that is now readily available for review by the public.

The release of these inspection citations is connected to the Open Government Initiative issued by President Obama on January 21, 2009. Pursuant to this initiative, the agency's stated purpose for now releasing this data set is to "improve the public's understanding of how the FDA works to protect the public health, provide the public with a rationale for the Agency's enforcement actions, and to help inform public and industry decision-making." Pursuant to this initiative, the data set provides information on general inspection citations under all areas of FDA jurisdiction. ^{2/}

Specifically, for each inspection, the data set includes:

- Firm name
- City/State/Country
- Date of the inspection
- Regulatory citation corresponding to the alleged violation (e.g., 21 C.F.R. 110.10(b)(3))
- Short general description (e.g., "Not washed/sanitized when appropriate")
- Long general description (e.g., "Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.")

Notwithstanding this new table of disclosed information, it is important to understand what *is* and *is not* included. On a typical Form 483, there is both: (a) a general citation as to the nature of the observation, usually in words that track the applicable FDA regulation; and (b) specific facts from the facility that were observed during the inspection and the FDA investigator believes support the

^{1/} The data set is available at <https://tinyurl.com/483observations>.

^{2/} FDA cautions that the citations disclosed in the data set are those associated with complete and finalized inspections, and are pulled from FDA's electronic inspection tools. For manually prepared Form 483s, and for any changes made to a Form 483 that was not synchronized with the electronic inspection tools, the data set will not fully reflect the Form 483 given to the firm.

general citation. The general citation *is* included in this new document. However, the more specific information about the inspector's observations at the facility *is not* included in this disclosure.

The release of this data set is notable because this information has previously only been publicly accessible through a Freedom of Information Act (FOIA) request, which is a time consuming process. Now that the data set has been posted on FDA's website, the information is readily accessible to the public. It may be a helpful resource (e.g., when performing supplier verification under FSMA or vetting potential acquisition targets), but also could raise concerns that information from the document potentially could be used against the company (e.g., by putative plaintiffs or the press). We encourage all food companies to review the document so that they are aware of the information regarding their facilities.

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Please let us know if you have any questions or if we can provide assistance helping you understand what this development means for your company and actions you can take in response to it.