FDA Publishes Form 483 Summary from the Last Decade

PUBLISHED ON
April 6, 2018

The Food and Drug Administration has publicly posted almost 185,000 citations potentially committed by businesses across the country through the last decade - even though the information in the posted report previously had been more difficult to obtain.

That could be a public relations nightmare for businesses on the list, and all businesses that fall under FDA regulations should consider viewing the list before current and potential customers do.

Nearly 185,000 citations are listed in the spreadsheet posted in March. Examples of some potential violations observed include employees failing to wash their hands thoroughly, plant buildings that may not prevent contamination, employees eating and drinking in areas where food products are exposed, proper monitoring procedures not established, and failure to appoint a particular management representative. Each firm cited has their city and state listed, as well as the date the inspection was completed, and any observations that indicate potential violations.

FDA inspections conclude with the inspector likely approaching the firm's management with the Notice of Inspectional Observations, otherwise known as Form 483. Form 483 contains a non-exhaustive list of conditions that, in the inspector's judgment, may constitute a violation of the Food, Drug and Cosmetic Act and/or any FDA regulations. In other words, any condition that **may** cause a product to be adulterated, misbranded, or injurious to public health may be included in this report.

Generally, the inspector discusses the Form 483 findings with the firm's management, and the firm is expected to institute procedures to correct the conditions in question. A firm may submit a written response, which the FDA may consider when deciding to take further corrective action. Depending on the severity of the potential violation, FDA may issue a warning letter. Neither Form 483 nor the warning letter constitute final agency action, and do not require the FDA to offer the firm an opportunity for a hearing. Thus, firms do not have the ability to dispute the information contained in past Form 483 observations that has recently been released.

Both Form 483 notices and warning letters can have serious implications for a firm from a public relations standpoint. Both documents are public knowledge, but until the FDA published the extensive summary late last month, only warning letters were readily accessible. Warning letters are published almost immediately on the FDA's website, but release of a Form 483 required a request under the Freedom of Information Act.

The recently increased availability of this information may, in some respects, be concerning for FDA regulated businesses. Freedom of Information Act requests are public information, so businesses in the past have been able to identify those looking into the claims, such as research groups, media outlets, venture

capital firms, competitors and especially plaintiff's lawyers. With the release of the Form 483 citations list, anyone - including your customers, insurers and certifying agencies - can access this information with a few mouse clicks. As we all know, a Form 483 notice which your firm may have received in the past may contain information which is inaccurate or may reference conditions that were addressed long ago. No business on the list is left unexposed to the implications of the release of this information.

If you have concerns about the recently published list of Form 483 citations, please contact me or anyone in Barley Snyder's Food & Agribusiness Group.

:

EmmaRose Strohl

Associate

Tel: (484) 318-2494

Email: estrohl@barley.com