Things That Make You Go Hmmm – Part II: Not Responding to an FD-483 in a Timely Manner

Alan G. Minsk

Approximately ten years ago, I wrote an article entitled, "Things That Make You Go Hmmm," inspired by a photograph of my then-three-year old son with his hand on his cheek in a contemplative pose. That article was about common mistakes some life science companies make when handling Food and Drug Administration (FDA) inspections – mistakes which left me scratching my head in amazement. Ten years later, I still scratch my head when I read about companies failing to respond to FDA inspectional deficiencies in a timely manner.

FDA has said that companies should respond to inspectional observations (noted on an FDA 483 Form) within 15 business days of receipt.[1] The agency has also stated that, if a company does not respond within this 15-day period, it may not review the response when evaluating whether to issue a Warning Letter:

> If we receive a response to FDA 483 observations more than 15 business days after the FDA 483 was issued, we do not plan to routinely include a response on the apparent adequacy of the firm's corrective actions in the warning letter. Rather, we plan to evaluate the response along with any other written material provided as the direct response to the warning letter (a firm's response to a warning letter may reference any of the firm's earlier responses).[2]

Despite such pronouncements, some companies still do not respond in a timely fashion and face the consequences. For example, FDA has written:

> Your firm's responses … to the Form FDA 483 (FDA 483) were not reviewed because they were not received within fifteen business days of issuance of the FDA 483. These responses will be evaluated along with any other written material provided in response to the violations cited in this Warning Letter.[3]

AGG Observations

1. There is no requirement to respond to an FDA 483 within 15 business days. However, FDA notes there can be consequences. Each company should remember that it is essential to demonstrate to FDA that it is committed to compliance and working to resolve any deficiencies as soon as possible. A failure to respond timely may be perceived by FDA as quite the opposite.
2. FDA does not expect all observations in an FDA 483 to be addressed within 15 business days, particularly if there are a number of outstanding issues. Rather, the 15-day timeframe is an opportunity for a company to digest the observations, consider next steps to fix any problems, start on corrective actions, and provide the agency a gameplan for addressing FDA's concerns that shows diligence and credibility.

1 74 Fed. Reg. 40211 (August 11, 2009).
2 Id. at 40212.
3 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm515375.htm (last accessed September 16, 2016); http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm515471.htm (last accessed September 16, 2016).

3. If a company determines it needs more than 15 days to respond due to, for example, the absence of key personnel, a holiday, or some unforeseen circumstance, contact the agency for an extension, with an explanation. We would not recommend a request on day 15 with no new deadline proposed. Any extension request should be made well in advance of the 15-day deadline, with a new reasonable expected response date (e.g., no more than another week). FDA is not required to grant an extension request but, in our experience, with sufficient notice, a new deadline offered, and a reasonable explanation for the request, the agency will try to be cooperative.
4. It might be coincidence, but it appears that many of the companies that fail to meet the 15-day expected deadline are companies outside of the United States. While there might be a number of explanations and reasons for speculation, the bottom line is that FDA expects a response within 15 business days. Therefore, plan accordingly.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

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