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ALERTS

FDA Issues Draft Guidance On Requesting Nonbinding Feedback After An Inspection

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The FDA recently issued a draft guidance document titled "Nonbinding Feedback After Certain FDA Inspections of Device Establishments." The guidance seeks to explain how a medical device firm can request nonbinding feedback on proposed remedies to address observations the FDA has made on Form FDA 483, the Inspectional Observations Form, after an inspection.

The FDA is accepting comments on this draft document until April 19, 2019.

Parameters for Nonbinding Feedback

In 2017, Congress amended the Food, Drug & Cosmetic Act to allow medical device firms to request nonbinding feedback from the FDA when a facility inspection identifies compliance issues. The firm can propose remedial actions to bring its facility into compliance and request the FDA's feedback on the adequacy of the measures before incurring the expense of implementing any corrective actions.

Not all observations on a Form 483 are eligible for nonbinding feedback. The draft guidance interprets the statutory criteria to require the FDA to issue nonbinding feedback only when the Form 483 includes observations that:

- require resolution because the conditions have resulted in, or if unaddressed, are likely to result in, the release of a violative

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product that may cause death or serious injury;

- the quality system or subsystem(s) deficiencies have resulted in, or would likely result in, the production of nonconforming, violative, and/or defective finished devices; or,

- relate to an emerging safety issue that, if unresolved, is likely to result in release of devices that are likely to cause death or serious injury

A request for nonbinding feedback should include a detailed explanation of how at least one of these criteria is met.

The draft guidance states that requests for feedback should be submitted within 15 days of the issuance of Form 483, which is the same time the response is due. Such requests should come from the person to whom the Form 483 was issued and should be addressed to the FDA employee identified to receive the response.

Content of Request

According to the draft guidance, the request should also state the inspectional observation(s) for which feedback is requested, followed by the proposed remedial measures for the observation(s). The proposed measures should include a detailed description and timeline of the activities the firm plans to take to correct the observed conditions and prevent their recurrence.

The FDA's Response

Within 45 calendar days of receipt of the request, the FDA will either (1) advise the firm that the observations are not eligible for nonbinding feedback or (2) provide the feedback. According to the draft guidance, if the FDA determines the proposed actions appear partially adequate or inadequate, the FDA intends to:

- acknowledge the proposed actions submitted;
- explain why the proposed actions (or elements of the proposed actions) do not appear adequate; and
- provide a recommendation on what may be needed for the FDA to consider the proposed actions (or elements of the proposed actions) adequate.

The draft guidance closes by stating what is already implied in the term "nonbinding feedback," namely that the firm's implementation of the FDA's feedback does not prevent the FDA from citing the same (or other) inspectional observations in a future inspection or from taking additional regulatory action.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug & Device group, at 317-231-7392 or lynn.tyler@btlaw.com.