



April 20, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Rm 1061
Rockville, MD 20852

Submitted via <https://www.regulations.gov>

Re: Docket No. FDA-2025-D-1504, “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.”

Dear Dockets Manager:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 700 blood collection sites in more than 1,100 communities, providing close to 60 percent of the U.S., and a quarter of the Canadian, blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

ABC appreciates the opportunity to provide feedback on FDA's draft guidance, “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.” ABC also appreciates FDA providing guidance that “provides recommendations that manufacturing establishments should follow to prepare concise, factual, and effective corrective action responses to observations that FDA documents on an FDA 483 during an inspection.” ABC notes that the draft guidance is comprehensive and contains insights into relevant references from the FDA and quality standards to ensure blood centers are always ahead of any systemic issues detected in quality internal audits, external inspections, and incident trends. The draft guidance focuses on the goal of maintaining a 483-free inspection, and more importantly, the safety of the blood supply for patients.

I. ABC recommends FDA clarify that certain elements are not universally required for every Form 483 response and should be applied “only if applicable.”

While ABC is pleased that FDA is providing guidance to assist blood centers in responding to an FDA 483, we have some concerns regarding several elements FDA recommends for inclusion in their response. The draft guidance states, “the FDA 483 response should include a table of contents and at least the following elements,” and lists the required elements.¹ Some of these elements, as well as a table of contents, are unnecessary for the types of observations blood establishments typically receive. For an extensive or highly detailed FDA 483 with multiple observations or other items related to the inspection

¹ [Draft Guidance for Industry](#): “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection,” March 2026, pp. 3-5.

(e.g. discussion items), the recommended structure may be appropriate; However, it is generally unnecessary for a routine 483, with only a few observations, received by blood centers.

Accordingly, ABC recommends that FDA revise the draft guidance to clarify that the following “Response Format and Content” elements (section III. A. of the draft guidance) are not universally required for every Form 483 response and should be applied “only if applicable.”

- Table of contents: For a routine 483 received by a blood center, the inclusion of a table of contents is unnecessary and should be optional, based on the scope and complexity of the observations.
- A copy of the FDA 483 issued at the close of inspection: A blood center’s response to an FDA 483 generally restates the observation, followed by the center’s response, root cause, and corrective action. Therefore, submitting a copy of the FDA 483 issued at the close of inspection is unnecessary as FDA’s observation is already restated in the blood center’s response, and FDA has the 483 document in its possession.
- Any associated global investigation plans and reports: Blood centers typically do not create a global investigation plan. Individual items are investigated and outcomes included in the response.
- An executive summary: Blood centers typically do not to create an executive summary of all remediation activities. The need for inclusion of an executive summary should not be required, but instead based on the nature, scope, or complexity of the observations.
- Attachments related to the associated observation: Blood centers do not typically include attachments, e.g., documents, pictures, videos, diagrams etc. The need for inclusion of attachments should not be required, but instead based on the severity or nature of the finding.

Additionally, in response to section III. B. of the draft guidance:

- FDA encourages establishments to develop a communication plan: Blood centers typically do not need to develop a communication plan for ongoing remediation activities. The decision to develop a communication plan should be optional, and based on the nature, scope, or complexity of the observations.

II. ABC recommends that FDA establish a voluntary option allowing manufacturing establishments to submit a “letter of intent to respond” indicating their plan to provide a full response to an FDA 483.

In the introduction to the draft guidance, FDA states: “The purpose of this guidance is to assist drug manufacturers *who choose* [emphasis added] to respond to FDA when they receive an FDA Form 483 Inspectional Observations... at the conclusion of an inspection.” Since a response is not required, and to ensure FDA is aware that a blood center intends to respond to an FDA 483 when issued, ABC recommends that FDA include a voluntary option in the draft guidance for manufacturing establishments to notify the agency in writing of their intent to respond.

ABC appreciates the opportunity to comment on the draft guidance. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

Thank you for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,

A handwritten signature in cursive script that reads "Katherine Fry". The signature is written in black ink and is positioned below the closing "Sincerely yours,".

Kate Fry, MBA, CAE
Chief Executive Officer