



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-D-1504]

Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection:

Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.” This guidance is intended for foreign and domestic human and animal drug manufacturing establishments inspected by FDA whose drugs are regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The purpose of this guidance is to assist manufacturers who choose to respond to FDA when they receive an FDA Form 483 Inspectional Observations (FDA 483) at the conclusion of a drug inspection to assess conformity with current good manufacturing practice (CGMP) requirements.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2025-D-1504 for "Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a

written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive

label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4330, Silver Spring, MD, 20993-0002, 301-796-3257; Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911; John W. Diehl, Office of Inspections and Investigations, Food and Drug Administration, 1201 Main St., Ste. 7200, Dallas, TX, 75202-3939, 214-253-5288, OIIPolicyStaffs@fda.hhs.gov; or Center for Veterinary Medicine, AskCVM@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.” The guidance 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. FDA has previously received inadequate responses to FDA 483 observations due to a lack or omission of relevant data, excessive amounts of data, and/or failure to address the root cause of observations in the FDA 483. Poor quality or incomplete responses make it difficult for FDA to ascertain what the establishment has corrected since the inspection and to evaluate remediation activities. This difficulty has ramifications for FDA’s ability to help firms achieve voluntary compliance, take appropriate enforcement action, and most importantly, minimize exposing patients and the public to risks.

Adherence to FDA’s CGMP requirements as set forth in 21 CFR parts 210, 211, and 212 for drug products is essential. FDA recommends a systematic approach to a risk-based analysis of a firm’s operation to resolve the deviations from CGMP requirements observed during FDA inspections. The procedures recommended in this draft guidance are intended to help firms

understand the significance of the observations, identify root causes, determine risk to patients, and swiftly implement effective corrective actions. Section V of the draft guidance includes recommendations for resolving scientific or technical disagreements related to FDA 483 observations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR parts 210 and 211 (CGMPs) and 21 CFR part 212 (positron emission tomography CGMPs) have been approved under OMB control numbers 0910-0139 and 0910-0667, respectively. In addition, information collected by the Agency on a Form 483 is exempt from the PRA under 5 CFR 1320.3(h)(3) and 1320.4(a)(2); responses to a Form 483 from the subject of an ongoing inspection/investigation are exempt from the PRA under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR. 1320.4(a)(2).

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>,

<https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>,

<https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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