Contains Nonbinding Recommendations

Nonbinding Feedback After Certain FDA Inspections of Device Establishments

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact the Office of Regulatory Programs (ORP)/DRP2: Division of Establishment Support at 301-796-5476. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010. For questions about ORA implementation, contact ORAPolicyStaffs@fda.hhs.gov.

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U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Office of Regulatory Affairs

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2018-D-4711. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 17047 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

ORA

Additional copies are available from the Internet. You may also send an e-mail request to ORAPolicyStaffs@fda.hhs.gov.

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Nonbinding Feedback After Certain FDA Inspections of Device Establishments

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA is issuing this guidance document to comply with section 702 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which amended section 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The purpose of this guidance is to explain how the owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA Inspectional Observations Form (Form FDA 483) and issued to the firm upon completion of an inspection of the firm's establishment. This guidance identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how FDA evaluates and responds to such requests.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Section 704(h)(2) was added to the FD&C Act in 2017 to require FDA to provide nonbinding feedback in certain circumstances after an FDA inspection of a device establishment. Timely nonbinding feedback can help device firms determine whether proposed actions to address inspectional observations are adequate, possibly avoiding unnecessary investment in potential solutions not likely to satisfactorily address an inspectional observation.

FD&C Act section 704(h)(2) states:

> (A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.
> (B) A request described in this subparagraph is a request for feedback—
> (i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and
> (ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

III. Submitting a Timely Request for Nonbinding Feedback

To demonstrate that the request is being made by the "owner, operator, or agent in charge"[1] of the device establishment, the request should come from the person to whom FDA issues the Form FDA 483 or from someone who can otherwise demonstrate to the Agency that they are the owner, operator, or agent in charge of the establishment or a designated representative of such person(s) (hereafter, "requestors").

A request for nonbinding feedback must also be made in a "timely manner."[2] To be considered timely, requests for nonbinding feedback should be submitted no later than 15 business days after issuance of a Form FDA 483. If a firm is also submitting a response to a Form FDA 483,[3] FDA recommends that the response and request for nonbinding feedback be included in the same submission but as two distinct documents.

Requests for nonbinding feedback should be submitted to the same FDA contact who is identified to receive the submission of a response to the Form FDA 483.[4]

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[1] FD&C Act section 704(h)(2)(B)(i).
[2] FD&C Act section 704(h)(2)(B)(i).
[3] See https://www.gpo.gov/fdsys/pkg/FR-2009-08-11/pdf/E9-19107.pdf.
[4] FDA investigators provide written instructions about how and where to submit responses to a Form FDA 483 at the end of the inspection. Requestors should use the same contact information identified in those instructions.

The request for nonbinding feedback should include:

- An email subject line or cover letter with a header that clearly and conspicuously states "Request for Nonbinding FDA Feedback After a Device Inspection;"

- The name, address, phone number, and email address of the person submitting the request;

- The name, address, and FDA Establishment Identification (FEI) number of the establishment that was inspected and the date(s) of the inspection; and

- A justification describing how the request meets at least one of the eligibility criteria specified in FD&C Act section 704(h)(2)(B)(ii), as described in Section IV below.

IV. Statutory Eligibility Criteria for Nonbinding Feedback

A request for nonbinding feedback under section 704(h)(2) must describe how one or more observations "involve a public health priority," "implicate systemic or major actions," or "relate to emerging safety issues (as determined by [FDA])."[5]

The following describe situations where FDA believes the request for nonbinding feedback meets these statutory criteria:

- The FDA-documented observation(s) in the Form FDA 483 involve a public health priority and require resolution because such conditions have resulted in, or if unaddressed are likely to result in, the release of a violative product that may cause death or serious injury.

- The FDA-documented observation(s) in the Form FDA 483 indicate that systemic or major deficiencies with the quality system or subsystem(s), when considering all pertinent factors, have resulted in, or if unaddressed are likely to result in, the release of nonconforming, violative, and/or defective finished devices that may pose a serious risk to public health.

- The FDA-documented observation(s) in the Form FDA 483 relate to an emerging safety issue that, if unaddressed, is likely to result in the release of devices that are likely to cause death or serious injury.

[5] FD&C Act section 704(h)(2)(B)(ii).

V. Justification of Request

The request for nonbinding feedback should contain a justification why the requestor believes at least one of the eligibility criteria described in Section IV is met. This justification may relate to an individual inspectional observation for which the nonbinding feedback is being requested, more than one observation, or all of the observations. Requestors should explain in detail how each individual observation for which nonbinding feedback is requested meets one or more of the eligibility criteria within the justification. Under the statute, FDA is required to provide nonbinding feedback on those observations in the request for nonbinding feedback that meet at least one of the statutory eligibility criteria. If none of the eligibility criteria are met, the statute does not require FDA to provide nonbinding feedback regarding proposed actions related to the observation.

VI. Proposed Responsive Actions

The request for nonbinding feedback should clearly state the inspectional observation(s) for which nonbinding feedback is being requested, followed by the proposed actions in response to the observation(s). The proposed actions should include a detailed description and timeline of the activities the firm plans to take to completely and adequately correct the conditions described in the observations and prevent recurrence. For FDA to properly evaluate the adequacy of any proposed actions to address the observations, the submission should also include supporting documentation, as appropriate.

VII. Nonbinding Feedback

Upon receiving a timely request for nonbinding feedback and verifying that the request has been made by the owner, operator, or agent in charge of the device establishment or a designated representative of such person(s), FDA determines whether one or more of the statutory eligibility criteria (see Section IV) have been met. To do so, FDA considers the justification provided in the request. If none of the eligibility criteria are met, FDA notifies the requestor within 45 calendar days that the request is not eligible to receive nonbinding feedback.[6] Otherwise, the statute requires FDA to provide nonbinding feedback about the proposed actions for addressing inspectional observations within 45 calendar days of the Agency's receipt of the request.

FDA's nonbinding feedback should identify whether the proposed actions to address inspectional observations, if appropriately implemented, appear adequate, partially adequate, or inadequate. If FDA determines the proposed actions appear partially adequate or inadequate, FDA intends to:

[6] While the statute does not require FDA to provide nonbinding feedback for untimely requests or requests for nonbinding feedback that do not meet the statutory eligibility criteria under section 704(h)(2) of the FD&C Act, FDA may choose to respond to these requests through an alternate mechanism (e.g., written correspondence, teleconference, face-to-face meeting) at its discretion.

1. Acknowledge the proposed actions submitted, including references (where appropriate) to sections, page numbers, or tables;

2. Explain why the proposed actions (or elements of the proposed actions) do not appear adequate; and

3. Provide a recommendation of what may be needed for FDA to consider the proposed actions (or elements of the proposed actions) adequate.

If FDA determines that the proposed actions (or elements of the proposed actions) appear adequate based on the information provided, FDA intends to notify the requestor. FDA's nonbinding feedback represents the Agency's best recommendation for the establishment's specific factual circumstances based on the information provided in the request for nonbinding feedback and other information known at that point in time. FDA's nonbinding feedback is intended to be used to inform the firm's implementation of actions in response to inspectional observations. Firms are not required to adhere to the nonbinding feedback provided by FDA; a firm may use an alternative approach to correct inspectional observations.

FDA's nonbinding feedback, if implemented, may not adequately address the cause of the problems that led to the inspectional observations, and additional action may be warranted. Implementation of FDA's nonbinding feedback does not prevent FDA from citing the same or other inspectional observations or otherwise taking regulatory action. FDA's nonbinding feedback does not preclude or limit FDA's regulatory options. It is the responsibility of the owners, operators, and agents in charge of the device establishment to ensure compliance with applicable laws and regulations administered by FDA.

VIII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated to average 500 hours per response. Send comments regarding this burden estimate or suggestions for reducing this burden to:
FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0886 (expires 04-30-2023).