Contains Nonbinding Recommendations

Review and Update of Device Establishment Inspection Processes and Standards

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Guidance for Industry

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For questions about this document contact the Office of Regulatory Affairs (ORA) Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov.

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

Contains Nonbinding Recommendations

Preface

Public Comment

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Review and Update of Device Establishment Inspection Processes and Standards

Guidance for Industry

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 to comply with section 702(b)(2) of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which directs FDA to issue guidance that specifies how the Agency will implement uniform processes and standards[1] that are applicable to inspections (other than for-cause)[2] of foreign and domestic device establishments.[3] FDA updated processes and standards as needed to address the new provisions in section 704(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that were added by FDARA section 702(a) and to establish a standard timeframe for inspections. This guidance also describes standardized methods of communication during the inspection process and identifies practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

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

[1] As used in this guidance, the term "standards" refers to "a level of quality or attainment" and does not refer to a "voluntary consensus standard" as described in Office of Management and Budget Circular No. A-119 at https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf.

[2] Section 704(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) applies to "inspections other than for-cause inspections" only. Therefore, as used in this guidance, "inspection" does not include for-cause inspections. The inspections within the scope of this guidance are conducted in accordance with a risk-based schedule pursuant to section 510(h)(2) of the FD&C Act.

[3] The uniform processes and standards in this guidance apply to inspections of device establishments required to be registered with the Secretary, including but not limited to establishments required to register under 21 CFR 607.80 and 21 CFR 1271.1(b)(2).

cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

On August 18, 2017, FDARA was signed into law. Among other things, FDARA added section 704(h)(1) to the FD&C Act. This provision requires FDA to review processes and standards applicable to inspections of domestic and foreign device establishments and update such processes and standards, as necessary, through the adoption of uniform processes and standards applicable to such inspections. Section 704(h)(1) of the FD&C Act specifies that the updated uniform processes and standards will describe how FDA should, among other things, pre-announce inspections of device establishments within a reasonable time before the inspection begins, provide a reasonable estimated timeframe for inspections, and ensure regular communication with the owner, operator, or agent in charge of the establishment during inspections.

Section 702(b) of FDARA instructs FDA to issue this guidance to describe how it is implementing section 704(h)(1) of the FD&C Act, provide for standardized methods of communication when communication is required under 704(h)(1), establish a standard timeframe for inspections, and identify practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

III. DISCUSSION

Pursuant to section 704(h)(1) of the FD&C Act, as added by FDARA, FDA reviewed the processes and standards applicable to inspections of foreign and domestic device establishments that were in place as of August 18, 2017. The review encompassed FDA guidances, manuals, programs, and internal standard operating procedures related to device establishment inspections. As a result of this review, FDA identified uniform processes and standards and drafted revisions to update procedural documents, including the Investigations Operations Manual and training materials, where necessary, to align with these processes and standards.

FDA believes that uniformity in investigators' approaches to inspections, both before and during, may inform firms' preparation for the inspection and set baseline communication and timing expectations for each party. The processes and standards identified below should facilitate practices that encourage continuity within an inspection and consistency across inspections. Section 704(h)(1)(A) of the FD&C Act allows FDA to establish exceptions to the updated processes and standards, as appropriate.

Pre-announcement Notice and Communication

FDA intends to make reasonable efforts to make contact with the firm to preannounce the inspection. Under the uniform processes and standards, an investigator notifies the owner, operator, or agent in charge of a device establishment by telephone before their facility

undergoes an inspection. While FDA intends to seek acknowledgement of the pre-announcement notification from the firm, FDA believes the firm's failure to acknowledge the notification should not be a reason to delay the start of an inspection. Under the statute, this notification will be provided within a reasonable time before the inspection is scheduled to occur. For domestic inspections, the pre-announcement should be no less than five calendar days in advance of the inspection. The pre-announcement for foreign inspections is generally more than five calendar days due to the requirements of particular country clearances. For both domestic and foreign inspections, the notification should include information about the type and nature of the inspection, such as whether the inspection is scheduled as surveillance or pre-approval.

Updated processes specify that during pre-announcement, investigators should communicate with the firm regarding the planned timeframe and duration of the inspection, to include appropriate working hours during which the inspection is likely to take place. To the extent possible, FDA should also provide advance notice of some records that may be requested during the inspection (e.g., certain procedures and any associated records).

Under 704(h)(1) of the FD&C Act, FDA retains authority to conduct unannounced, for-cause inspections.

Standard Inspection Timeframe

FDA standards for reasonable estimated timeframes of inspections generally range from 3 to 6 continuous business days. These standards are based on the type of surveillance inspection (abbreviated or comprehensive) and the extent of coverage needed for a pre-approval inspection. The estimated duration for each inspection should be shared with the firm at the time of pre-announcement. Inspection duration is impacted by factors such as the complexities of the firm's operations, availability of knowledgeable staff, and the nature of observed deficiencies.

Additionally, it may be necessary to extend the duration of an inspection for a number of reasons, including for FDA to follow-up on post-market safety information such as recalls, Medical Device Reports, and complaints received by the Agency. Updated processes provide that, unless an investigator or the firm identifies a reason that additional time is needed and communicates this verbally to the other party, inspections of both domestic and foreign device establishments should take place within a standard timeframe and occur over consecutive business days. FDA recognizes that circumstances may arise, for either FDA or the firm, where exceptions to these timeframes may be appropriate. Exceptions to the timeframe should be communicated verbally during the course of the inspection.

Communication During Inspections

FDA's updated processes also address regular verbal communications during the inspection between the investigator and the owner, operator, or agent in charge of the device establishment about the status of the inspection. When time and circumstances permit, investigators should make every reasonable effort to discuss all observations with the owner, operator, or agent in

charge of the device establishment as they are observed, or on a daily basis, to minimize errors and misunderstandings. These discussions may address observations not documented on the FDA Form 483 that require clarification. Communications may be recorded by either FDA or the firm, if there is advance notice and mutual consent by the other party.[4]

[4] FDA recordings will be treated in accordance with applicable disclosure laws including sections 301(j) and 520(c) of the FD&C Act (21 U.S.C. 331(j), 360j(c)) and the Freedom of Information Act (5 U.S.C. 552).