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Draft – Not for Implementation

Review and Update of Device Establishment Inspection Processes and Standards

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Draft Guidance for Industry

DRAFT GUIDANCE

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Document issued on March 29, 2019.

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For questions about this document contact the 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
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Preface

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Review and Update of Device Establishment Inspection Processes and Standards

Draft Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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FDA is issuing this draft guidance to comply with section 702(b)(1) of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), which directs FDA to issue draft guidance that specifies how the Agency will implement uniform processes and standards[1] that are applicable to inspections[2] (other than for-cause) of foreign and domestic medical device establishments. 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 This draft guidance also describes standardized methods of communication during the inspection process, and identifies practices for investigators and device establishments to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FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidance describes 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.

[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 FD&C Act applies to "other than for-cause inspections" only. Therefore, as used in this draft guidance, "inspection" does not include for-cause inspections.

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) 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 establishment owner, operator, or agent in charge during inspections.

Section 702(b) of FDARA instructs FDA to issue this draft guidance to describe how it is implementing section 704(h)(1), 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 medical 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 medical device establishment inspections. As a result of this review, FDA identified uniform processes and standards and drafted revisions to 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 across inspections. Section 704(h)(1)(A) allows FDA to establish exceptions to the updated processes and standards, as appropriate.

Pre-announcement Notice and Communication

Under the uniform processes and standards, an FDA investigator notifies the owner, operator, or agent in charge of a medical device establishment by telephone before their facility undergoes an FDA surveillance and/or pre-approval inspection. Under the statute, this notice will be provided within a reasonable time before the inspection is scheduled to occur. For domestic inspections, the pre-announcement should generally be no less than five calendar days in advance of the inspection. The pre-announcement for foreign inspections may be more than five days due to

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 abbreviated, comprehensive, or pre-approval.

Updated processes specify that during pre-announcement, investigators may communicate with the firm regarding the 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. Under 704(h)(1), 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 FDA investigator and the owner, operator, or agent in charge of the establishment about the status of the inspection. When time and circumstances permit, investigators should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize errors and misunderstandings. These communications may be recorded by either FDA or the firm, if there is advance notice and mutual consent by the other party.