AdvaMed
Advanced Medical Technology Association

701 Pennsylvania Avenue, NW
Suite 800
Washington, D.C. 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. FDA-2019-D-0914; Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry

Dear Sir or Madam:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide comments on the Food and Drug Administration ("FDA" or "Agency") draft guidance, "Review and Update of Device Establishment Inspection Processes and Standards" (Draft Inspection Guidance").

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed's member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments.

AdvaMed commends FDA for publication of the Draft Inspection Guidance. The draft guidance addresses the FDA Reauthorization Act's ("FDARA") mandate to "…adopt[ion of] uniform processes and standards applicable to such inspections" Draft Inspection Guidance, lines 99-100. To this end, we offer general comments on the draft guidance, followed by comments related to specific parts of the guidance.

General Comments

FDA's Inspection Schedule should be Risk-Based and Consider the Participation of the Subject Company in International Device Audit Programs.

The Draft Inspection Guidance should specifically recognize the risk-based process for device inspections, as it is important for allocating FDA's inspectional resources. Risk-based inspections for devices is not a new concept and, in many cases, FDA already follows this principle. Its elimination from this draft guidance might lead some to believe that a different principle or principles are to be followed in inspections in the future. Including the risk-based concept in the draft guidance will send a clear and unequivocal message that the principle of risk-based inspections is to be continued.

Further, FDA is participating in the International Medical Device Regulators Forum ("IMDRF") Medical Device Single Audit Program ("MDSAP"). The medical device industry is finding this

program to be of great value in reducing the redundant inspections conducted by various governments' regulatory agencies. The inspections conducted under this program include all FDA requirements and results of these inspections are made available to FDA. A company that participates in this program and has been the subject of a successful inspection should not be required to undergo additional routine surveillance inspections by FDA as long as the MDSAP inspection has occurred within the past two years. Companies' participation in the MDSAP program enables FDA's utilization of its individual resources to address for "cause inspections" as well as pre-approval inspections. To that end, when FDA conducts a "for-cause" inspection at a facility that has successfully undergone an MDSAP inspection within the past two years, the "for-cause" inspection should be limited in scope to the specific issues for which the inspection was initiated, unless during the course of the" for cause" inspection, FDA identifies systemic issues that require further follow-up.

Inspections performed under the Electronic Product Radiation Control ("EPRC") provisions of the Food, Drug, and Cosmetic Act ("FDCA") are expected to be included in the MDSAP program, per the Center for Devices and Radiological Health ("CDRH"). When this occurs, we would also expect FDA to consider this when scheduling FDA inspections of device facilities. In its response to these comments, if FDA could clarify the timing of inclusion of EPRC requirements into MDSAP, it would be greatly appreciated.

The Draft Guidance Should Include Criteria to Assist FDA Investigators to Maintain Uniform Processes and Standards

As stated in the draft guidance, FDARA Section 704(h)(1) instructs FDA to adopt uniform processes and standards for inspection of medical device facilities. These should include pre-announcement of inspections, estimated timeframe for inspections and regular communication during the inspection.

AdvaMed agrees with these objectives, which assist companies in understanding FDA operations and expectations for all inspections that are not "for cause." The draft guidance states that inspections should be pre-announced, generally no less than 5 days prior to the inspection; that FDA should provide information about the type and nature of the inspection and should communicate with the firm about appropriate work hours during which the inspection will take place. FDA also should provide advance notice of some records that may be requested during the inspection, provide a reasonable estimated timeframe for the inspection, and should ensure regular communication with the establishment owner, operator, or agent in charge during the inspection.

21 U.S.C. section 374 (h)(1)(A) provides that the Secretary of HHS may make exceptions to the uniform processes and standards for inspections required under section 704 (h)(1). The Draft Inspection Guidance, however, uses very broad terminology to describe the exceptions. For example, ""…the pre-announcement *should generally* be no less than five calendar days in advance…"; "…investigators *may communicate* with the firm regarding the appropriate working hours during which the inspection is likely to take place."; [*T]o the extent possible* , FDA should also provide advance notice of some records that may be requested…;" "[*W]hen time and circumstances permit*, investigators should make every reasonable effort to discuss all observations…as they are observed or on a daily basis…"[emphasis added]. It is important to note that section 374, in providing that the Secretary of HHS may make exceptions, does not contemplate that the individual investigator or the investigator's superiors will make ad hoc decisions about exceptions to the uniform processes and standards. In contrast, the draft guidance strongly suggests that exceptions can be made on an ad hoc basis. AdvaMed recommends that the draft guidance be modified to include specific criteria to clearly explain when exceptions to the uniform processes and standards can be made. In addition, FDA's internal procedures should require supervisory review of any decision to deviate from these uniform processes and standards. In this way, both industry and the Agency will understand inspectional expectations clearly; these modifications will also increase the likelihood of these expectations being met.

FDA's Procedures should Include Metrics to Measure the Success of the Revised Inspectional Processes.

"What gets measured gets done" is an axiom known by many. Even though some of the practices in the draft guidance were already supposed to be in effect for device establishments well prior to 2017, the need for Congress to include section 704(h)(1) in FDARA shows that these practices were not uniformly applied. Consequently, AdvaMed strongly recommends that FDA establish goals for the Agency with respect to consistency and uniformity of inspection of device establishments and regularly review and publish these metrics. This action will further assure industry of FDA's commitment to uniform and consistent inspections and will enable the Agency and the public to track FDA's performance in meeting the goals of FDARA.

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In closing, we note that the Draft Inspection Guidance is not consistent with Least Burdensome principles. FDA's Least Burdensome guidance characterizes compliance related interactions as an example of compliance policies that promote Least Burdensome practices. "The Least Burdensome Provisions: Concept and Principles – Guidance for Industry and Food and Drug Administration Staff," p. 7. As noted above, uniform inspection processes and standards provide the industry and Agency with clear expectations that help to assure the most effective use of facility inspections as well as the efficient use of FDA and industry resources. The current wording of the draft guidance, however, provides FDA with so much flexibility to deviate from these processes and standards that they are rendered meaningless. Our proposed revisions correct this shortcoming and align the inspection process with FDA's Least Burdensome obligation.

AdvaMed thanks FDA for its consideration of these general comments and the specific comments that follow in the attachment. Please do not hesitate to contact me at 202-434-7228 or jtrunzo@advamed.org if you have any questions.

Respectfully Submitted,

/s/

Janet Trunzo
Senior Executive Vice President
Technology & RegulatoryAffairs
AdvaMed

Specific Comments on the Draft Guidance on Review and Update of Device Establishment Inspection Processes and Standards Docket No. FDA-2019-D-0914; Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry

Comment Number	Lines	Proposed change	Rationale
1		Add the following wording to the example on line 86: "Furthermore, as required by section 701 of FDARA, FDA intends to take a risk-based approach when scheduling audits, other than for-cause audits that, among other factors considers the participation of the device establishment in international device audit programs. By taking a risk-based approach to scheduling inspections and providing added transparency and consistency in the process, FDA is modernizing its policies to efficiently use valuable resources, ensuring timely access and maintaining patient safety."	By recognizing both sections 702 and 701, FDA demonstrates its commitment to wise utilization of agency resources as well as maintaining product quality and patient safety.
2	132-134	"…notifies the owner, operator, or agent in charge of a medical device establishment by telephone before their facility	Pre-announcement should include acknowledgement that the establishment has received notification of the inspection. There are numerous reasons why a call may not adequately convey the required notification, including company

		undergoes an FDA surveillance or pre-approval inspection." Add "If the call is not answered, FDA shall wait for acknowledgement from the establishment, within reason."	holiday, personnel vacation, wrong telephone number, etc. A standard protocol for notification, including a list of the information that is to be provided, will help assure the consistency FDA desires.
3	132-134	FDA may also want to consider adding additional means of communication such as e-mail.	To assure that companies are appropriately notified.
4	132-146	A description of the document types FDA will request during the inspection should be added to required communication.	This will facilitate preparation for the inspection and contribute to its efficiency.
5	133	FDA should develop a protocol for situations where the primary contact is unavailable. This should describe what happens in situations where the telephone call is not answered and no response is received.	This will clarify how FDA addresses circumstances that affect communication with the manufacturer, as well as providing clear expectations for communication with the manufacturer.
6	136	"…pre-announcement should generally be no less than five calendar days in advance…' should be changed to "…pre-announcement should generally be no less than five business days in advance…"	U.S. companies typically have four calendar days off at Thanksgiving and many are shut down between Christmas and New Year. Five calendar days is insufficient notification to gather requested documents and assure the presence of key personnel when weekends and holidays are considered.
7	139	FDA should develop a standard list of information that will be included in the inspection notification. This should include name of inspector/s, date of	This information will provide clarity to the company and enable the company to assure the appropriate number and type of resources will be available.

		inspection, type of inspection, and duration of inspection.	
8	140	Add "…whether the inspection will be abbreviated, comprehensive, pre-approval, if "for cause" or not."	This information will assist the company in preparation for the inspection, as well as supporting the estimate for length of inspection.
9	142	Change "Investigators may communicate…" to "Investigators shall communicate."	This sets a clear expectation for investigators and companies.
10	142	Include a brief description of how these processes tie into and are concurrent with the risk-based model FDA follows for inspection of device facilities.	This provides a clear and important correlation between the practices and a risk-based inspection model.
11	150	Modify the sentence to state "A comprehensive surveillance inspection will be no greater than 6 days, occurring consecutively, unless unforeseen circumstances affecting either FDA or the firm occur.	Regardless of type of inspection, complexity of products or company operations, FDA virtually always completes foreign inspections in 5 days or less. The same should be true for U.S. companies.
12	158	Modify wording to state "…post-market information such as Class I recalls…"	Absent a significant public health risk, inspections based on class II or III recalls serve as a disincentive for companies to act appropriately when recall is needed. Thus, Class II or III recalls that are firm-initiated and do not carry risk to public health should not be the basis for an inspection.
13	174	Add a requirement that communications recorded either by FDA or a manufacturer will not be disclosed to other parties.	This change would provide clarity regarding the use of notes taken by either party over the course of the inspection.