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June 25, 2019

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

Re: Docket No. FDA-2019-D-0914; Review and Update of Device Establishment Inspection Processes and Standards; Draft Guidance for Industry

On May 28, 2019, the Advanced Medical Technology Association (“AdvaMed”) provided comprehensive comments on the Food and Drug Administration (“FDA” or “Agency”) draft guidance, “Review and Update of Device Establishment Inspection Processes and Standards” (Draft Inspection Guidance”). Also, on May 28, FDA provided a 30-day extension for comments on this draft guidance to be submitted. This letter provides an additional General Comment.

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.

General Comment

The Food and Drug Administration Reauthorization Act (“FDARA”) of 2017 (Pub. L. 115-52, section 702(b)) mandates that FDA implement consistent processes and standards for inspections of medical device establishments. These include providing advance notice of inspections, including the type and nature of the inspection, and some of the records that may be requested; establishing a standard timeframe for the inspection; and providing for regular communication during the inspection.

AdvaMed requests a clarification in FDA’s draft guidance to provide that these medical device requirements will apply to the inspection of any device or device component of a combination product, regardless of the FDA Center that has jurisdiction over the device.

FDA’s Center for Biologics Evaluation and Research (“CBER”) has review and inspectional authority for some medical devices and in vitro diagnostics, primarily those that are used in blood banks. FDA’s Center for Drug Evaluation and Research (“CDER”) has review and inspectional authority for some combination products that include a device component; the same is true of CBER. As FDA is aware, FDARA’s provisions specifically cover establishments that design, manufacture, assemble, process, package, label, or store medical devices without distinguishing those regulated by the Center for Devices and Radiological Health (“CDRH”) from those regulated by CDER or by CBER.



In the current Investigational Operations Manual (2019), FDA states that “Preannouncements may be considered for establishments that manufacture both drugs and devices or biologics and devices.” In fact, AdvaMed believes that preannouncements for these inspections are mandated by FDARA unless the investigator will not be inspecting the devices or device components manufactured or held in the facility. In addition, the other requirements of FDARA that are specific to medical devices, including: following a risk-based schedule for inspection; considering the participation of the establishment in international device audit programs; providing a reasonable estimate of the time frame for the inspection; providing advance notice of some records that may be requested; establishing regular communications during the inspection; and providing non-binding feedback on inspectional responses as requested, are required regardless of the Center that is leading or participating in the inspection.

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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/

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