November 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Re: Docket No. FDA-2019-D-3769; Draft Guidance for Industry and FDA Staff: Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment in response to the Food and Drug Administration’s (FDA’s or Agency’s) Draft Guidance for Industry and FDA Staff: “Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act” (hereinafter Electronic Submissions Draft Guidance).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 are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

General Comment

We appreciate FDA’s issuance of this draft guidance. Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), amended by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-521), requires that industry provide many types of device submissions to FDA in electronic format to be specified by FDA by a date to be announced in final guidance. The statute directed FDA to issue draft guidance by October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of, and exemptions from, the requirements.

In addition, in the MDUFA IV commitment letter, FDA committed to developing “electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process” and “[by] FY 20 [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates.”

FDA states that the draft guidance satisfies both the statutory commitment to issue draft guidance on electronic submission format standards and the MDUFA IV commitment to issue draft guidance on electronic templates. However, the majority of the draft guidance discusses electronic formats and the FDA states in the draft guidance that it would not be feasible to outline the electronic format for all
submissions covered by the statutory provision in a single guidance. Instead, it states which types of submissions will be subject to submission in electronic format and commits to issuing independent guidances for each of those types of electronic submissions, including opportunity for comment. We appreciate FDA’s commitment to provide for an opportunity to comment on those independent guidances and expect to have comments on those individual guidance documents when they are released for public comment.

We recommend FDA adopt a practice of full transparency with industry regarding its plans for submissions by electronic format. IT systems are complex and costly and new systems require validations to be completed and new procedures and processes to be created. All of these activities are labor and time intensive and costly. The better industry understands FDA’s vision and expectations, the smoother this transition will be, benefiting all stakeholders.

We request that in developing the electronic format standards that FDA provide as much flexibility as possible, e.g., recommendations for content and file naming conventions without mandating one specific software. Many companies have well-established templates, tools, and processes for publishing submissions, and frequently use common content across global markets. A flexible approach would help streamline and optimize internal processes and decrease submission timelines and burden.

We also request that FDA provide a reasonable transition time to implement and validate (generally 18 months) FDA specifications and keeping specifications static during the transition time period. The draft guidance describes a large number of submission types that will require electronic submission. It is not clear if the agency plans to create electronic templates for each of these submission types or whether it will implement other IT submissions processes. We would encourage FDA to develop template recommendations for all of the submission types listed as subject to electronic format in the future and to release with the draft individual guidances draft electronic submission template or IT requirements/specifications. Concurrent release of the electronic submission template is necessary to evaluate and comment on the draft guidance document. This is especially important in the early phases as industry is learning what FDA expects of an electronic submission format.

If FDA does not opt to create a template for each type of submission required in electronic format, as an alternative, we would request that FDA clarify for which submissions FDA is planning to issue electronic templates, including which ones will have in vitro diagnostic (IVD)-specific templates. In our past experience with FDA templates, such as eSubmitter, indicated there are different data elements between IVDs and other medical devices. We understand FDA may be pursuing a separate IVD 510(k) electronic submission template and encourage the agency to continue this activity and make the template available for the industry to evaluate before finalizing guidance with timetables. We recommend FDA seek user feedback when designing electronic submission templates to address functional items, such as the size of files that can be attached to the template, text box character limitations, the ability to copy and paste tables into a template, attaching data files such as SAS or Excel, and the ability to reference multiple standards.
As FDA designs electronic submission templates, we ask the agency to please consider that industry must be able to establish mechanisms for internal review and comment prior to submitting to FDA and archiving submissions that are human readable.

AdvaMed thanks FDA for its consideration of these general comments and the specific comment that follows. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully submitted,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs

Attachment
Additions indicated in underline.

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<th>Line No</th>
<th>Proposed Change</th>
<th>Comment/Rationale</th>
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<tr>
<td>157</td>
<td>Laser Product Reports, Supplemental Reports, Abbreviated Reports and Annual Laser Report</td>
<td>We would like FDA to also develop standards for laser reports.</td>
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