Dear Sir or Madame:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide comments on the Food and Drug Administration (“FDA”) draft guidance, “Recognition and Withdrawal of Voluntary Consensus Standards; Draft Guidance for Industry and Food and Drug Administration Staff” (“Draft Standards Recognition Guidance”).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.

We support the use by FDA and other global regulatory authorities of international voluntary consensus standards to meet regulatory requirements, which furthers efforts to harmonize global medical technology regulations. “Standards play a significant role in the design, production, post-production and regulation of medical devices throughout their lifecycle. Important tools for conformity assessment, standards facilitate and support innovation and help ensure that devices are safe and perform as intended. Standards offer a means to streamline and harmonize regulatory processes around the world, especially as medical devices grow in complexity and international markets expand. Standards can be particularly valuable as they ‘… generally reflect the best experience of industry, researchers, consumers and regulators worldwide, and cover common needs in a variety of countries….’”1

We appreciate FDA’s issuance of this draft guidance to reflect the process for requesting recognition of standards, the response process, and principles to consider in order to help implement the 21st Century Cures Act, Sec. 3053. Recognition of Standards.

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1 Optimizing Standards for Regulatory Use, IMDRF Standards WG/N51 FINAL: 2018 (citing the International Electrotechnical Commission).
General Comments

We recommend that FDA provide explanations for any transition period shorter than 36 months.

We believe that when the duration of the transition period is less than three years, FDA should provide a clear rationale for the shorter transition timeframe (e.g., factor ‘X’ has been found to present a major safety issue during the application of the standard). The setting of insufficiently lengthy transition periods can cause a manufacturer substantial difficulties to address what is not a correspondingly significant issue or impact to a patient. The integration of new expectations into product design, verification, validation, labeling and updated regulatory documents can be a time-consuming and resource-intensive effort. We would recommend that FDA consistently provide explanation for accelerating this effort.

We would encourage FDA to add language indicating that it will consider harmonization in recognition and withdrawal decisions.

The statute directs FDA, in updating standards recognition guidance, to take “into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.” Given the important role that standards play in harmonization, we would recommend that FDA include language that is similar to this statutory language in the guidance.

FDA should endeavor to harmonize end of transition periods with other global regulatory authorities.

To the extent possible, the end date of a transition period should align with the date of withdrawal established for equivalent European, Canadian or other international adoptions of the same standard. As discussed above, harmonizing standards recognition internationally is a benefit to both regulators and industry. International harmonization of transition periods will result in a least burdensome application of standards for both FDA and manufacturers.

We request that FDA revise the language regarding the 60-day deadline per the statute.

Per the statute, FDA “shall make a determination” “not later than 60 calendar days after” it receives the request. By contrast, the draft guidance states that “FDA’s goal is” to make a decision on recognition no more than 60 calendar days after receipt. We would recommend that the Agency revise this sentence to more closely reflect the statutory language.

We recommend that where parts of a standard are not recognized, FDA provide a clear explanation/rationale for why that part is not recognized.

The draft guidance contains helpful language regarding the rationale that FDA would provide, per the statute, if it decides to not recognize the standard. We believe that a similar explanation would be helpful to elucidate why FDA has decided not to recognize part of the standard. Such rationales would support differences that may occur within submission documents used for multiple geographies. Manufacturers need to clearly understand the rationales/reasons for why some sections are or are not recognized, to be able to apply to internal documentation that may be used both within and outside of the United States.
We suggest that FDA add language to the guidance explaining that a manufacturer may use a standard in the FDA database prior to the issuance of the standard in the Federal Register.

We appreciate FDA’s inclusion in the recent Final Guidance: Appropriate Use of Voluntary Consensus Standards (“Final Appropriate Use Guidance”) the concept that a manufacturer does not need to wait for the issuance of the recognition in the Federal Register but can begin to use a standard when it is listed as recognized in the FDA standards database. We think this is a very helpful concept as significant time can elapse between when FDA decides to recognize a standard and when the standard can publicly issue in the Federal Register. Critical time can be lost in the ability to utilize a standard as “recognized” if manufacturers do not learn of it becoming “recognized” in a timely manner.

We would recommend that language on this point from the Appropriate Use Guidance similarly be added to this guidance to help publicize this useful approach. Finally, we would support the development of other mechanisms to help sponsors and other interested stakeholders learn of a forthcoming recognition, for instance, an email list serve announcing significant updates to the FDA recognition database to interested subscribers.

We would propose updating language in the guidance to reflect the European Medical Device Regulation.

The draft guidance notes that adherence to standards “is an optional method of meeting ‘essential requirements’ within the European Union’s regulatory scheme.” Essential Requirements under the Active Implantable Medical Device directive (“AIMD”) and Medical Device Directive (“MDD”) will soon be replaced by the General Safety and Performance Requirements (“GSPR”) per the new European Medical Device Regulation (“EU MDR”). We would recommend updating the guidance to reflect this upcoming change.

Specifically, we would propose one of the following revisions: (1) adherence to standards “is an optional method of meeting the General Safety and Performance Requirements (“GSPR”) under the European Medical Device Regulation (“EU MDR”)” or (2) adherence to standards “is an optional method of meeting the essential requirements under the Medical Device Directive (“MDD”) or Active Implantable Medical Device directive (“AIMD”) or the General Safety and Performance Requirements (“GSPR”) under the European Medical Device Regulation (“EU MDR”), within the European Union’s regulatory scheme.”

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AdvaMed thanks FDA for the issuance of this draft guidance and for its consideration of these comments. Use of international voluntary consensus standards for regulatory purposes helps minimize unnecessary costs and delays in patient access to innovative new devices, and we appreciate FDA’s important efforts regarding standards recognition. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully Submitted,

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Jamie Wolszon
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Technology & Regulatory Affairs