

June 26, 2018

*By Electronic Delivery*

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 17 Fishers Lane, Rm. 1061  
Rockville, MD 20852.

**RE: Docket No.: FDA-2018-D-1339**  
Draft Guidance, *Clinical and Patient Decision Support Software*  
Comments of the Consumer Technology Association

To Whom It May Concern:

The Consumer Technology Association (“CTA”) respectfully submits these comments regarding the Food and Drug Administration’s (“FDA” or “the Agency”) April 27, 2018, draft guidance document, *Multiple Function Device Products: Policy and Considerations*.

CTA is the principle trade organization for the consumer technology industry, comprised of more than 2,000 member companies covering a broad range of technology segments. CTA also owns and produces CES® –the world’s gathering place for all who thrive on the business of consumer technologies. Profits from CES are reinvested into CTA’s industry services. In particular, of relevance to these comments, CTA represents many companies operating in the digital health and medical technology space in the United States. CTA’s Health and Fitness Technology Division strives to grow the health, fitness and wellness technology category. We do this in part by working to ensure that health and fitness technology devices, services, and apps operate in a clearly defined regulatory environment that balances innovation with safety and privacy.

CTA thanks FDA for issuing this important guidance, which provides clarity on an issues that is

of critical importance to the consumer technology sector. Given the prevalence and availability of consumer electronic devices, adding medical functionality to these devices and software products offers opportunities to increase accessibility of important tools for addressing numerous health issues, such as monitoring chronic disease. If adding that functionality would result in unregulated functionality becoming regulated, there would be a significant disincentive for companies to develop these medical technologies. Thus, the Agency's draft guidance represents an important step in facilitating innovation and development.

Given the importance of these policies, CTA applauds FDA for going beyond the policy articulated in the 21<sup>st</sup> Century Cures Act (Cures Act), which was limited only to software products. By extending the same principles to the assessment of all multiple function products, including hardware devices, the Agency is appropriately incentivizing continued product innovation that incorporates valuable medical functionalities. CTA appreciates the Agency's effort to clarify these policy issues and take a least burdensome approach to regulation, focusing regulatory oversight only on functionalities most warranting FDA's attention.

In keeping with CTA's appreciation for the Agency's efforts, we would like to bring to FDA's attention a few questions and issues that our members believe may warrant further consideration in order to make the final guidance optimally useful.

#### **I. Clarification of the Types of Relationships that Do Not Have an "Impact" Would be Helpful**

The guidance defines a multiple function device product as containing "at least one device function and at least one other function." A "function" is defined as a "distinct purpose of the product, which could be the intended use or a subset of the intended use of the product." Although not explicitly defined, the guidance appears to suggest that a "device function" is a function that falls within the definition of a medical device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The guidance further defines "other functions" as those functions that:

- (1) do not meet the definition of a device,
- (2) meet the definition of a device but are not subject to premarket review, e.g., 510(k)-exempt, or
- (3) meet the definition of a device but for which FDA has expressed its intention to not enforce compliance with applicable regulatory controls.

The guidance indicates that “FDA does not regulate certain software functions contained in a multiple function device product as a device because they do not meet the statutory device definition.” The guidance further indicates that “FDA intends not to review a device function subject to an enforcement discretion policy merely because it is part of a multiple function device.” CTA agrees that this regulatory approach is consistent with the least burdensome principles.

The guidance also indicates that FDA may “assess the impact of the other function” when evaluating the safety and effectiveness of the device function-under-review and that the sponsor “should include a description of the other functions which impact the device function-under-review, and how they impact it.” This appears to imply that a sponsor need not include in the premarket submission information regarding any “other function” that does not impact the device function-under-review, as would be consistent with the least burdensome principles.

FDA explains that the “existence of a relationship does not necessarily mean that there may be an impact [by the other function] on the safety or effectiveness of the device function-under-review.” CTA appreciates FDA’s recognition that all functions within a single product will almost always be related to some extent merely by the fact that they are included in the same product and that this fact alone should not increase the focus on the unregulated functions. CTA also appreciates FDA’s provision of a list of considerations for determining whether an unregulated function may impact the safety or effectiveness of the device function-under-review. However, to avoid the uncertainty about whether such a function impacts a device function-under-review and to ensure consistent interpretation across the different review branches, additional insight on the specific types of relationships that would be considered as not having an “impact” would be extremely useful. Clarity regarding expectations is important for both industry and internal FDA review staff.

## **II. FDA Should Clarify the Required Discussion of “Other Functions” in Premarket Submission**

FDA explains that “[w]here the device function-under-review is not adversely impacted by an “other function,” FDA does not intend to assess that other function (unless the Sponsor would like FDA to consider the positive impact of the other function in FDA’s assessment of the device function-under-review).” CTA appreciates the examples provided in Appendix 2 of “other functions” that adversely impact the device function-under-review and the types of documentation that would be required to show that an increased risk or adverse effect from the combination of functions has been mitigated. However, to avoid the uncertainty about whether an “other function” adversely impacts a device function-under-review and to ensure

consistent interpretation across the different review branches, this could be further clarified in the final guidance.

First, it would be useful for industry if the final guidance includes examples of “other function” that would be considered to *not* have an adverse impact on the device function-under-review, even though it may have some neutral or positive impact. Second, it would also be extremely useful for the Agency to explain the extent any “other function” that does not have an adverse impact on the device function-under-review should be included or discussed in a premarket submission or internally documented.

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CTA appreciates this opportunity to comment on FDA’s *Multiple Function Device Products: Policy and Considerations* draft guidance. CTA supports FDA’s efforts to clarify how devices in this category will be regulated moving forward, and hopes that these comments are helpful in explaining some of the industry’s concerns and recommendations as the Agency prepares the final version of the guidance.

We would be pleased to answer any questions you might have about these comments. Please contact me at 703-907-7544 or [mpetricone@CTA.tech](mailto:mpetricone@CTA.tech) or Kinsey Fabrizio at 703-907-4341 or [kfabrizio@CTA.tech](mailto:kfabrizio@CTA.tech) if CTA can be of any assistance.

Sincerely,

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