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By Electronic Delivery

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

RE: Docket No.: FDA-2017-N-4301-0001
FDA Software Precertification Program
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") recently released working model version 0.2 for the Software Precertification Program ("Pre-Cert").

CTA is the principal 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.

Since FDA's announcement last July of its Digital Health Innovation Action Plan, CTA has closely followed the Agency's efforts to develop a Pre-Cert program for medical device software that would allow companies with demonstrated excellence to pursue more streamlined pre-market review of their products. To that end, CTA previously submitted comments on the earlier working model version 0.1. CTA continues to believe that this program is incredibly important given the continued advancement of technology and the potential to provide valuable new tools for helping manage and treat many different diseases and conditions. CTA fully supports this initiative and offers the comments on version 0.2 below to aid FDA in the continued development of the program.

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I. ADDITIONAL CLARIFICATION OF THE MINIMUM EXPECTATIONS FOR EXCELLENCE APPRAISAL WOULD BE HELPFUL

CTA agrees with FDA's recognition that the underlying principles of the excellence appraisal need to be consistently interpreted and applied across industry, and that there must be some flexibility in the specific mechanisms by which excellence and compliance with the spirit of the program can be demonstrated. CTA further appreciates the Agency's outline of organizational domains and elements of the Excellence Principles in Appendix B of the working model. While flexibility is useful as the Agency develops version 1.0 of the working model, in order to ensure consist application across participants and to build trust in the program, additional clarity as to minimum expectations will be helpful. CTA recognizes that the program is still rapidly evolving, but notes that balancing flexibility with clarity is very important for the ultimate success of the program.

Furthermore, the working model indicates that FDA hopes to implement "automation for the acceptance and review of an organization's demonstration of their elements in future iterations to reduce appraisal burden, increase transparency, and enhance the capability to respond quickly and improve products without reducing public confidence in the program." Additional details regarding the planned "automation," including any record-keeping expectations, would be helpful.

Consistent with CTA's earlier comments on version 0.1 of the working model, CTA believes that a comprehensive decision tree that identifies which minimum expectations and key performance indicators (KPIs) may apply to a particular type or profile of SaMD developer would be helpful. For example, the decision tree may begin with all SaMD developers and then branch to specific entity types/profiles (*e.g.,* start-up versus large-distribution operation, or machine learning versus more standard software technology), with different KPIs targeted for the different entities/profiles. This step-wise approach would allow for flexibility yet also ensure consistency in interpretation and application among developers and within the Agency.

Relatedly, CTA would like to reiterate its prior comments that succeeding in this endeavor will require FDA to be transparent in how conformance to the excellence principles is interpreted with respect to particular organizations. To that end, CTA recommends that FDA document its appraisal assessments and resulting precertification determinations in a manner that allows future applicants to better understand the relevant criteria, *e.g.,* monthly or bimonthly brief summaries of how prominent/ambiguous issues were reviewed and decided—without disclosing proprietary information.

II. FDA SHOULD DEFINE DEVELOPERS OF "PRODUCTS" TO CLARIFY ELIGIBILITY FOR LEVEL 2 CERTIFICATION

CTA continues to support the Agency's bifurcation of organizations into Level 1 and Level 2 Certification. CTA appreciates the Agency's change from the version 0.1 working model to distinguish between SaMD developers that have successfully marketed and maintained "products"—as opposed to "medical devices"—and those that have not. CTA agrees that this change is likely to result in a more inclusive threshold and that an organization without a medical device or SaMD currently on the market should have the opportunity to deliver products for medical purposes as a pre-certified organization. However, it would be helpful if FDA would further define the types of "products" that would be relevant in determining eligibility for Level 2 Certification. While it may well make sense to consider, for example, successful commercialization of non-FDA regulated Health IT products, it is unclear whether the Agency's use of the term "product" would extend to any type of product.

Related to CTA's comment above, with respect to the excellence appraisal process and criteria, it would be helpful for the Agency to clarify whether different appraisal standards would apply to developers who have marketed and maintained a certain "product" that is not a medical device, and if so, how those standards may differ. Such clarification could be incorporated into the excellence appraisal decision tree proposed above.

III. ADDITIONAL CLARIFICATION AS TO REVIEW PATHWAY DETERMINATION AND PRODUCT LEVEL TRANSPARENCY IS NEEDED

CTA supports FDA's plans to develop a risk-based framework so that pre-certified organizations developing SaMD can determine the premarket review pathway for their products. Specifically, CTA appreciates that such framework will include a flow chart or decision tree that identifies elements, methods, and processes for pre-certified organizations to use in determining the appropriate review pathway based on the risk of the product. CTA agrees that premarket review for a pre-certified organization's SaMD should be informed by the organization's precertification status, precertification level, and the SaMD's risk-category leveraging the International Medical Device Regulatory (IMDRF)'s risk-categorization framework.

With regards to the product level elements, the Agency indicated its expectation that all program participants would be transparent in providing information on their SAMD(s), including certain enumerated elements relating to risk, product modifications, and real-world performance data. However, it is not clear when and how such information would be provided by the organization—whether it would be provided publicly, provided to FDA when the organization determines that pre-market review is required, or internally documented when the organization believes that pre-market review is not needed. Clarification as to the context, timing, and extent of such expectations would be helpful.

While CTA appreciates the Pre-Cert program's goal of encouraging transparency, CTA believes that such goal should be balanced against the administrative and cost burden placed upon SaMD organizations and should be implemented consistent with the least burdensome principle. In addition, CTA believes that—as is the case in other areas of FDA regulation—when and how to document these product level elements should largely depend on the level of risk posed by a particular SaMD product.

IV. ESTABLISHING METRICS SURROUNDING THE ITERATIVE EARLY ENGAGEMENT STREAMLINED PROCESS WILL BE HELPFUL

CTA commends the Agency's efforts in dedicating resources to developing an early engagement process in which the Agency and SaMD organization can collaborate to develop and quickly bring to market safe and effective SaMD. As with the current pre-submission program, CTA believes that an early engagement streamlined process has the potential to be extremely helpful in effectively and efficiently guiding the organization's product development. However, to help FDA better manage the iterative early engagement process and to ensure that the process satisfies the collective overarching goal of getting SaMD products to market more quickly compared to the existing pre-market submission process, CTA suggests that FDA establish metrics to compare the iterative early engagement streamlined process to the current pre-market submission process. For example, FDA could track whether the iterative early engagement process shortens the overall time it takes to go from initial contact with the Agency to receiving market clearance for a product.

V. ADDITIONAL CLARIFICATION REGARDING REAL WORLD PERFORMANCE DATA REQUIREMENTS IS NEEDED

CTA appreciates FDA's clarification and examples of the real-world performance data requirements. CTA agrees that an interactive FDA review and mutual agreement to a proposed RWPA plan is necessary in order to afford flexibility and tailoring of such plan to the specific type of organization, and the SaMD reviewed. CTA also supports the continued refining of the RWPA process. To that end, CTA is providing specific feedback to examples in Appendix D of the working model version 0.2 in hopes that such feedback will help the Agency continue to develop these real-world performance data requirements.

First, it is not clear whether the indicated "All stakeholders" values are within the realm of control of SaMD developers. It would be helpful if the Agency could clarify what is meant by the "All stakeholders" values discussed in Appendix D.

Second, CTA recognizes that appropriate KPIs will vary for different organizations and SaMD products. However, certain of the KPI examples provided could be difficult, if not impossible, to

measure and report upon. For example, the Agency provides as an example KPI for the "Human Factors and Usability Engineering" domain measuring user error rate. As with other software products, it would be difficult to quantify, or even qualify, users' errors when using a software product short of monitoring use of the SaMD in-person and in real-time. Similarly, certain metrics may not be obtainable due to privacy concerns or users opting out of data collection. Clarification of how the Agency would handle these scenarios would be helpful.

Third, CTA suggests that the Agency consider, consistent with the least-burdensome principle, the cost-effectiveness of monitoring and measuring various KPIs. Certain KPIs, such as user retention or time in app, may be good to know but also involve a heavy cost and administrative burden on the SaMD developer that outweighs the minimal value from the knowledge gained. Furthermore, as CTA suggested in its earlier comments to version 0.1, pre-certified organizations should be permitted to leverage existing RWPD processes to reduce submission burden rather than generate new data solely for FDA purposes.

VI. FDA SHOULD CLARIFY HOW IT WILL ENFORCE REPORTING OF CORRECTIONS AND REMOVALS IN RELATION TO THE REAL-WORLD PERFORMANCE DATA ANALYTICS REQUIREMENTS FOR PRECERTIFIED ORGANIZATIONS

The current working model indicates that RWPA requirements will include product performance analytics to demonstrate the accuracy, reliability, and security of a SaMD product with a goal of having more timely patches and updates to correct software bugs and security vulnerabilities. To the extent that product performance analytics (PPA) monitoring activities may overlap with the regulations at 21 CFR 806.10 (Reports of Corrections and Removals) and 21 CFR 820 (Quality System Regulation), it would be helpful for the Agency to clarify how a pre-certified organization's effective PPA monitoring program may influence the method and manner of FDA's enforcement of the above regulations. For example, FDA could consider relaxing or waiving certain reporting requirements if PPA monitoring will already entail reporting similar information to FDA on a regular basis. Similarly, clarification as to the record-keeping requirements for PPA monitoring versus corrections and removals that are not required to be reported would be helpful.

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CTA appreciates this opportunity to comment on FDA's proposal for precertification of software developers, and hopes that these comments are helpful as the Agency continues to fine-tune the working model. As FDA itself has noted, the approach proposed for the new Pre-Cert program is much more suited to the faster, iterative design, development, and type of validation used for

SaMD. With a few modifications and added granularity, we believe it has tremendous potential to move industry, and health care, forward.

We would be pleased to answer any questions you might have about these comments. Please contact me at 703-907-4341 if CTA can be of any assistance.

Sincerely,

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