CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Via electronic submission

Re: Draft Guidance for Industry and Food and Drug Administration Staff on Multiple Function Device Products: Policy and Considerations (Docket No. FDA–2018–D–1339)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) submits these comments in response to the U.S. Food and Drug Administration's (FDA's or Agency's) draft guidance, *Multiple Function Device Products: Policy and Considerations* (April 27, 2018) (Draft Guidance).[1] For more than 137 years, CHPA has served as an effective and vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter (OTC) medical products. CHPA members' products provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA welcomes FDA's Draft Guidance as an important first step in clarifying section 3060(a) of the 21st Century Cures Act (Cures Act), which amended the Federal Food, Drug, and Cosmetic Act (FDCA) to add section 520(o). Among other things, this new FDCA section describes the regulation and assessment of a software product with multiple functions, including at least one device function and at least one software function that is not a device. CHPA appreciates FDA's acknowledging in the Draft Guidance that the Agency intends to

[1] *See* 83 Fed. Reg. 18570 (Apr. 27, 2018); *see also* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM605683.pdf.

apply the same principles to the assessment of all multiple function products that contain at least one device function (ln. 193-196).[2]

Need for More Detailed Input and Clarity

While we applaud FDA's issuing this Draft Guidance and explaining the Agency's regulatory approach and policy for all multiple function device products, CHPA would like to raise a fundamental issue with the Draft Guidance for FDA's consideration. Specifically, CHPA believes that the document is very high-level and does not provide useful details or examples, especially with regard to technical issues. While we recognize that FDA believes "there is no one-size-fits-all approach for the wide variety of multiple function device products" (ln. 249-50), CHPA recommends that a final guidance contain additional detail that permits the industry to more readily apply the principles in the Draft Guidance to their own products. In particular, it would be useful to include in any final guidance at least one example of a device connected to software applications, such as games that provide feedback to children on whether the device is being used properly, and information about whether the Agency has additional expectations about demonstrating safety in this population even when the essential device function remains unchanged.

Moreover, the Draft Guidance does not provide sufficient information concerning postmarket documentation practices for certain non-reviewed device functions. For example, the table in Appendix 1 (summary of the premarket and postmarket policy for Multiple Function Device Products) lists certain device functions that are not reviewed by FDA, but that are assessed only for impact on the safety and effectiveness of the device function-under-review. CHPA understands that general control requirements apply to device functions that are 510(k) exempt, and that the agency intends not to enforce the general control requirements for device functions in cases where FDA has announced its intention to exercise enforcement discretion with regard to applicable regulatory controls. CHPA requests clarification regarding the expected postmarket documentation (if any) for non-reviewed device functions for which FDA does not intend to enforce applicable regulatory controls. For example, is the manufacturer responsible for investigating to what extent the non-reviewed function may have contributed to a software-related cybersecurity vulnerability caused by the device function-under-review? In addition, what type of information would the agency expect to see regarding such an investigation?

Additionally, the Draft Guidance's current format is confusing and difficult to follow. In particular, we suggest that a final guidance include one or more flowcharts to outline how FDA will assess the impact of other functions on the device function-under-review (Section VI of

[2] *See also* 83 Fed. Reg. at 18571 ("Although section 520(o)(2) of the [FDCA] applies to the regulation of software products containing at least one device function and at least one non-device function, FDA believes the same principles apply to all multiple function products that contain at least one device function").

the Draft Guidance). In creating a more robust final guidance, we also believe that FDA should include a comprehensive list of Agency guidance documents and FDA-recognized consensus standards that may relate to the topics covered in the Draft Guidance.[3] Attachment I to these comments outlines possible software-related Agency guidance documents and FDA-recognized consensus standards for inclusion in the final guidance.

Additional Concerns

In addition to our fundamental concerns outlined above, CHPA includes two recommendations for the final guidance: (1) clarify that sponsors are permitted to include non-device functions in the indications for use statement, and (2) detail how a manufacturer should assess modifications to cleared or approved multiple function device products. Finally, we include some miscellaneous comments.

I. In the final guidance, FDA should explain that sponsors are permitted to include non-device functions in the indications for use.

In Section VII.A of the Draft Guidance, FDA states that in a premarket submission the "indications for use should *only* include the indications for use of the device function-under-review" (ln. 377-378).[4] The Agency then explains that the "device description" should include a "description of other functions that impact the device function-under-review, and address how the device function-under-review is impacted by each of the other functions. Sponsors should describe how each of the other functions is meant to be used, and in what ways they impact the device function-under-review" (ln. 381-384).

The outlined approach creates an inconsistency between the device description and the indication for use in that the description will reference functions that are not under review, but these functions cannot be acknowledged in the indications for use statement, even though they contribute to the device's indication. This construct results in significant limitations in the ability to adequately describe an indication for products that rely on multiple functions, especially those products where only a few functions are regulated or reviewed by FDA.[5] For example, if a product includes a software function that permits the display of medical device data that is not regulated by the Agency, it appears that under the Draft Guidance the sponsor could not reference the display of data from the device in the indications for use statement.

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[3] *See, e.g.*, FDA, "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005), *available at* https://www.fda.gov/downloads/MedicalDevices/.../ucm089593.pdf.

[4] (emphasis added).

[5] If a particular product has six different functions but only one is a device function-under-review, then under the Draft Guidance the indications for use would only mention that one function. By not providing context for the five other functions, the indications for use could potentially be misleading and/or confusing.

However, if the display of data is part of the system that will be marketed, the manufacturer may want to include this feature in this indication for use statement. Moreover, consumers may be confused by the lack of a cross-reference or correspondence between the indications for use and the device description.

FDA's own examples in the Draft Guidance also demonstrate this limitation. In the skin detection software application example on page 15 of Appendix 2, a sponsor would not be permitted to mention in the indications for use statement the smart phone computing platform, nor the camera on the computing platform. But, the indications for use statement must be consistent with labeling, advertising, and instructions for use.[6] If labeling, advertising, and instructions for use mention the smart phone computing platform and the camera on the computing platform, but these functions are not included in the indication, this could create consumer confusion.

We recommend that FDA clarify in a final guidance that sponsors are permitted to include in the indications for use statement all device functions, whether or not they are under review.

II. FDA should also discuss in the final guidance how a manufacturer can assess modifications to cleared or approved multiple function device products.

The Draft Guidance does not address how a manufacturer should assess modifications to previously cleared or approved multiple function devices. In October 2017, FDA published two final guidance documents concerning how to decide whether a manufacturer should submit a new 510(k) or document a letter to file for a change to an existing device.[7] We recommend that any final guidance cross-reference the two October 2017 documents.

In particular, if a manufacturer modifies the device function-under-review, then the manufacturer should follow the recommendations laid out in the October 2017 guidance documents. Consistent with the Draft Guidance, if a manufacturer modifies the non-device function, the manufacturer should first assess whether there is an impact on the safety or effectiveness of the device function-under-review as a result of the other function. If there is an impact, then the manufacturer should follow the recommendations in the October 2017 guidance documents.

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[6] *See* FDA, "Content of a 510(k)" (Oct. 31, 2017), *available at* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm#link_6.

[7] *See* FDA, "Guidance for Industry and Food and Drug Administration Staff: Deciding When to Submit a 510(k) for a Change to an Existing Device" (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm514771.pdf; FDA, "Guidance for Industry and Food and Drug Administration Staff: Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514737.pdf.

Additionally, in the Draft Guidance, it is not clear to what extent the design history file (DHF) must contain information on changes or modifications to the non-device function or whether design control requirements apply to the non-device function. We recommend that FDA clarify in Appendix 1 (and elsewhere) that the non-device functions are *not* subject to the Agency's design control requirements.

III. Miscellaneous.

CHPA wishes to highlight the following additional issues concerning the Draft Guidance:

- It appears that certain aspects of the Draft Guidance (ln. 386-400) are not fully aligned with existing FDA final guidance, including *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices ("Software Guidance").*[8] For example, under that particular guidance, minor-level of concern software devices[9] do not require architecture design documentation or a software design specifications (SDS) document in a premarket submission.[10]

  The Draft Guidance, on the other hand, states that "[t]he architecture and design documents included in the premarket submission for the device function-under-review should include adequate detail to understand how or if the other functions interact with or impact the device function-under-review." (ln. 387-389). It is unclear how the Agency will treat Class II, minor-level of concern software in the context of multiple function products, and we request clarification on this question.[11]

- In the Appendix 2 examples, FDA does not explain what "documentation" should be submitted to the DHF and what information should be submitted for FDA premarket review. CHPA recommends that FDA provide further clarity here and in the final guidance more generally on this point.

- The Draft Guidance states that the Agency intends to apply the same principles to the assessment of <u>all</u> multiple function products that contain at least one device function. However, in Appendix 2, FDA provides limited non-software, non-device function examples. It would be helpful for industry to have additional non-software examples in Appendix 2.

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[8] FDA, "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

[9] FDA considers the level of concern to be "minor" if "failures or latent design flaws are unlikely to cause any injury to the patient or operator." *Id.* at 5.

[10] *Id.* at 9-10 (Table 3: Documentation Based on Level of Concern).

[11] Additionally, we request that the Agency add the term, "Hazard Analysis," to Section VII.D of the Draft Guidance. Such a term is used in the above-referenced 2005 guidance document.

Conclusion

CHPA thanks FDA for its first effort in clarifying the Agency's regulatory approach and policy for multiple function device products. CHPA wishes to continue to serve as a constructive partner on these issues and would be happy to meet with the Agency. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully submitted,

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Attachment I:

Agency Guidance Documents and FDA-Recognized Consensus Standards

- AAMI TIR69: 2017: Consensus Standard: Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems, August 21, 2017

- ANSI/IEEE C63.27-2017: American National Standard for Evaluation of Wireless Coexistence

- ANSI/UL 2900-2-1Ed.12017: Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

- FDA, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2014

- FDA, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 2005

- FDA, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005

- FDA, General Principles of Software Validation, January 2002

- FDA, Off-the-Shelf Software Use in Medical Devices, September 1999

- FDA, Radio Frequency Wireless Technology in Medical Devices, August 2013