CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

Submitted via www.regulations.gov

February 21, 2023

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

Re: Content of Human Factors Information in Medical Device Marketing Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; 87 *Fed. Reg*. 75635-75637. Docket No. FDA–2015–D–4599.

Dear Sir or Madam:

The Consumer Healthcare Products Association[1] ("CHPA") submits these comments on the Draft Guidance for Industry and Food and Drug Administration ("FDA" or the "Agency") Staff titled "Content of Human Factors Information in Medical Device Marketing Submissions" published on December 9, 2022 ("Draft Guidance").[2,3] For more than 142 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

The Draft Guidance provides a risk-based framework for the human factors information that should be included in a marketing submission to the Center for Devices and Radiological Health ("CDRH"). The Draft Guidance will supersede the Agency's prior February 2016 draft guidance "List of Highest Priority Devices for Human Factors Review."[4] The Draft Guidance complements the final guidance "Applying Human Factors and

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] FDA, Content of Human Factors Information in Medical Device Marketing Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 87 *Fed. Reg*. 75635-75637 (Dec. 9, 2022). Accessed from https://www.govinfo.gov/content/pkg/FR-2022-12-09/pdf/2022-26767.pdf on January 18, 2023.

[3] FDA, Content of Human Factors Information in Medical Device Marketing Submissions; Draft Guidance for Industry and Food and Drug Administration Staff (Dec. 9, 2022). Accessed from https://www.fda.gov/media/163694/download on January 18, 2023.

[4] FDA, List of Highest Priority Devices for Human Factors Review; Draft Guidance for Industry and Food and Drug Administration Staff (Feb. 3, 2016). Accessed from https://www.fda.gov/media/95804/download on February 20, 2023.

Usability Engineering to Medical Devices"[5] ("Final Human Factors Guidance"). When finalizing the Draft Guidance, FDA intends to concurrently revise the Final Human Factors Guidance to incorporate the definitions included in the Draft Guidance in lieu of the current definitions in the Final Human Factors Guidance and to replace the current discussion on documentation in the Final Human Factors Guidance (Section 9 and Appendix A) with cross-references to the Draft Guidance.

CHPA supports FDA's continued efforts to provide guidance on human factors information for inclusion in device premarket submissions. CHPA also generally agrees with the Agency's risk-based approach in defining different categories of human factors information for submission in device premarket submissions, and the types of considerations outlined in the Draft Guidance that may impact which category of information is appropriate for a particular submission. But when finalizing the Draft Guidance, CHPA strongly encourages FDA to provide further clarity regarding the appropriate human factors information in premarket submissions that involve a change from prescription use to over-the-counter ("OTC") use and associated changes from a predicate device as compared to modifications to a sponsor's own device.

First, CHPA recommends that FDA revise the Draft Guidance to include additional clarity as to the relevant considerations for submission of human factors information for changes from prescription use to OTC use for a device. CHPA recognizes that human factors information often plays an important role in supporting such switches. However, while the Draft Guidance does include a question in the decision tree related to new intended users and new intended use environments, the Draft Guidance does not address changes from prescription to OTC use. For example, in some cases, for a change from prescription to OTC use there may not be a change in the intended users and use environments, such as a change from prescription home use to OTC home use. Therefore, CHPA requests that when finalizing the Draft Guidance FDA include a discussion of the appropriate human factors information for premarket submissions that involve a change from prescription use to OTC use. It would also be useful to include this type of change in the decision tree and the examples. In addition, while the decision tree includes a change to the intended device users and intended use environments, none of the examples in the Draft Guidance address a scenario for a change that involves either a new intended users or new intended use environments. CHPA recommends that, when finalizing the Draft Guidance, FDA include these scenarios in the examples.

Second, CHPA encourages FDA to further clarify for 510(k) premarket submissions how the Agency differentiates between changes from a third-party predicate device and changes where the sponsor's own device serves as the predicate device. The first question in the decision tree for determining the human factors submission category is whether the device is a modification to an existing device. If a sponsor is modifying their own device, then Decision Point B asks about certain types of changes, such as changes in the user interface, intended device users, intended device uses, intended use environment, or labeling. On

[5] FDA, Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff (July 18, 2016). Accessed from https://www.fda.gov/media/80481/download on February 20, 2023.

the other hand, for a sponsor's first device, the decision tree does not refer to how that device may differ from a predicate device; rather the decision tree directs sponsors to evaluate whether there are critical tasks for the device. But it is unclear why the need for human factors information would differ for a device that is the same as the predicate device except for a change in the human interface based on whether the 510(k) for the predicate device was held by the same sponsor or a third party. That is, it is not clear why the need for human factors data to support the substantial equivalence of a new or modified device to the predicate device should depend on the sponsor for the predicate device. CHPA believes that the same considerations as to the nature of the changes from the predicate device would be relevant irrespective of whether a sponsor is modifying its own cleared device or relying on a third-party predicate. CHPA also notes that the examples in the Draft Guidance do not include any example for a 510(k) premarket submission for a new device—the Draft Guidance only provides several examples for modifications to a sponsor's own 510(k)-cleared device, and one example for information to be submitted in a Premarket Approval Application for a new device. Therefore, CHPA requests that FDA further clarify the full scope of human factors considerations for 510(k) premarket notifications that involve a change to a third-party predicate device. CHPA also requests that when finalizing the Draft Guidance the Agency include examples involving a 510(k) premarket notification with changes from the predicate device that is not the sponsor's own device.

* * *

CHPA appreciates the opportunity to provide suggestions to the Agency on the Draft Guidance and the Agency's approach to human factors information in device premarket submissions. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully Submitted,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2023.02.21 12:25:07 -05'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association
Email: mhoward@chpa.org
Phone: 202 429 3532 (office)

Cc: Tania Reina, MBA, Assistant Director, Human Factors, Division of Drug Delivery & General Hospital Devices and Human Factors, CDRH (via Tania.Reina@fda.hhs.gov)