CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

Submitted via www.regulations.gov

November 23, 2021

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

Re: "Electronic Submission Template for Medical Device 510(k) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff" 86 *Fed. Reg.* 53965-53967[1] (September 29, 2021); Docket No. FDA-2021-D-0872

Dear Sir/Madam:

The Consumer Healthcare Products Association[2] ("CHPA") submits these comments in response to the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") Draft Guidance for Industry and FDA Staff, "Electronic Submission Template for Medical Device 510(k) Submissions ("Draft Guidance").[3] CHPA welcomes FDA's efforts to modernize and streamline the process for creating and submitting 510(k) premarket notifications and generally supports the approach described in the Draft Guidance. However, CHPA recommends that FDA clarify the following key points when finalizing the Draft Guidance:

- The Draft Guidance states that it describes the standards associated with preparation of the electronic submission template for 510(k)s that "…will enable submission of the 510(k) electronic submission *solely in electronic format*." (emphasis added; see lines 184-185 of Draft Guidance) However, the Draft

[1] FDA, Electronic Submission Template for Medical Device 510(k) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability. 86 *Fed. Reg.* 53965-53967 (September 29, 2021). Accessed from https://www.govinfo.gov/content/pkg/FR-2021-09-29/pdf/2021-21135.pdf on November 22, 2021.

[2] 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.

[3] FDA, Electronic Submission Template for Medical Device 510(k) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability. Access from https://www.fda.gov/media/152429/download on November 22, 2021.

Guidance does not address the process for transmittal to FDA. As such, it is not clear whether FDA will also be developing a process for electronic transmittal of eSubmissions or whether sponsors will continue to download eSubmissions onto a physical storage medium (such as a compact disc or flash drive) and mail or deliver the physical storage medium to FDA, as is the current practice for eCopies and submissions under the eSTAR Pilot Program. While CHPA appreciates FDA's efforts to streamline the creation and formatting of the electronic 510(k) submission files, CHPA encourages FDA to also consider methods that would enable electronic transmittal of such submissions to streamline the process for delivery to and receipt by FDA.

- CHPA recommends that FDA clarify how eSTAR or other electronic submission templates will be used in creating electronic submissions for responses to Additional Information requests (which are currently required to be submitted as an eCopy). For example, would sponsors be expected to update the relevant portion of the eSTAR template and resubmit the full template? Would sponsors complete only the portion(s) of the eSTAR template relevant to the Additional Information request and submit a partial eSTAR submission? Or would sponsors continue to submit responses to an Additional Information request in the current eCopy format?

- CHPA also recommends that FDA clarify that the use of eSubmissions for the original 510(k) submission (and potentially responses to additional information requests) would not impact the current process for interactive review requests and responses via e-mail and telephone. CHPA believes the current interactive review process, which permits sponsors to submit responses to reviewer requests via e-mail, is effective in resolving review questions in a timely and efficient manner.

- To support sponsors' process for drafting and developing 510(k) submission content, CHPA recommends that the final electronic submission template retain the current eSTAR template's use of unstructured data and attachments for key narrative sections of the 510(k) submission, such as the Device Description and Substantial Equivalence Comparison. Because revisions and comments to information in structured data fields in the electronic submission template cannot be easily tracked, the ability to draft and edit these key sections is facilitated by the use of unstructured data and attachments.

CHPA appreciates the opportunity to provide comments on the Draft Guidance. 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: 2021.11.23 14:02:04 -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) | 202 494 6856 (cell)

Cc: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration (sent via email to Rebecca.Nipper@fda.hhs.gov); Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (sent via email to Stephen.Ripley@fda.hhs.gov)

Z:\Medical Devices\CMD Committee\FDA Submissions\510k e-Submissions\Final\CHPA_FDA CDRH Draft Guidance_510k e-Submissions_FINAL 11232021.docx