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November 19, 2024

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

Re: Predetermined Change Control Plans for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 89 Fed. Reg 67945, Docket No. FDA–2024-D-2338

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The Consumer Healthcare Products Association[1] ("CHPA") submits these comments on the Draft Guidance for Industry and Food and Drug Administration ("FDA" or the "Agency") Staff entitled "Predetermined Change Control Plans for Medical Devices" published on August 22, 2024 ("Draft Guidance").[2] For more than 143 years, CHPA has served as a vital advocate for the consumer healthcare products industry.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.

Section 515C of the Federal Food, Drug, and Cosmetic Act, as added by section 3308 of the Food and Drug Omnibus Reform Act of 2022, provided the Agency with new authority for Predetermined Change Control Plans (PCCPs) for medical devices. The Draft Guidance provides FDA's current thinking on a policy for PCCPs for medical devices and the Agency's recommendations on the information to include in a PCCP in a marketing submission for all medical devices.[3]

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[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 OTC 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[2] FDA, Predetermined Change Control Plans for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 89 Fed. Reg. 67945 (Aug. 22, 2024). Accessed from https://www.govinfo.gov/content/pkg/FR-2024-08-22/pdf/2024-18828.pdf on November 18, 2024. Draft Guidance accessed from https://www.fda.gov/media/180978/download on November 18, 2024.

[3] FDA previously issued separate draft guidance specifically addressing PCCPs for artificial intelligence and machine learning-enabled device software functions. FDA, Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning-Enabled Device

CHPA supports FDA's continued efforts to support medical device innovation by facilitating to the use of PCCPs for efficient Agency review of medical device modifications. When finalizing the Draft Guidance, CHPA strongly encourages FDA to provide further clarity regarding the content and process for PCCPs with respect to the following:

- The Draft Guidance states that if a 510(k) premarket notification seeks to demonstrate substantial equivalence to a predicate device with an authorized PCCP, the substantial equivalence comparison must be against the version of the predicate device as cleared, not the predicate device as modified in accordance with the PCCP.[4] But the Draft Guidance does not address how device manufacturers should generate this substantial equivalence comparison, particularly where comparative testing may be required and the 510(k) sponsor only has access to the currently marketed version of the predicate device that includes modifications under a PCCP. CHPA requests that FDA provide additional clarity as to how 510(k) sponsors should approach the substantial equivalence comparison, including any comparative testing, for predicate devices that have been modified pursuant to an authorized PCCP.

- The Draft Guidance states that FDA indicates that if a cleared 510(k) includes an authorized PCCP, then information on the authorized PCCP should be disclosed in the device labeling. Specifically, the Draft Guidance recommends that "the labeling include a statement that the device has an authorized PCCP," and that as modifications are implemented pursuant to the PCCP, that the labeling be updated to include: "a description of the implemented modifications, including a summary of current device performance, associated inputs/outputs, validation requirements and related evidence;" a "description of how the modifications were implemented;" and a "description of how users will be informed of implemented modifications, including example, updated instructions for use or a version history."[5]

  CHPA agrees that the labeling for the modified device should be updated consistent with the update procedures in the PCCP modification protocol and the modifications to the device (e.g., to update performance data, add new features, etc.). However, FDA does not explain the information about specific to a description of the PCCP and related modifications in the labeling is necessary for the safe and effective use of the device. When device manufacturers obtain a new 510(k) for a significant modification to their device, the labeling for the modified device would not typically include information regarding how

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Software Functions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 88 Fed. Reg. 19648 (Apr. 3, 2023). CHPA also submitted comments on that draft guidance.

[4] Draft Guidance at 11.

[5] Draft Guidance at 12.

modifications from the previously-cleared version of the device were implemented or how users will be informed of the modifications from the prior clearance to the new clearance. Rather, the labeling for the new 510(k) simply reflects the necessary instructions for use for the new device. So it is not clear why such information is necessary for modifications made to pursuant to a PCCP when it is not included for other significant modifications to a 510(k)-cleared device. CHPA requests that when finalizing the Draft Guidance FDA align the appropriate for labeling following a modification made pursuant to a PCCP with the approach to new device labeling for significant modifications implemented via a new 510(k) clearance.

To the extent FDA is concerned about changes to devices after the device has been distributed made pursuant to a PCCP, the Draft Guidance recommends that the PCCP modification protocol include update procedures to provide appropriate transparency and users. CHPA believes it would be appropriate for such procedures to follow the same considerations as other significant device enhancements manufacturers may release for distributed devices following a new 510(k), but that special descriptions of how modifications are implemented pursuant to a PCCP are not necessary.

- In the Draft Guidance, FDA reiterates that new unique device identifiers (UDIs) are required for devices that are required to bear a UDI on its label when there is a new version and/or model, and for new device packages.[6] CHPA requests clarification that labelers should follow the same processes for determining when there is a new version and/or model of a device as a result of modifications made pursuant to an authorized PCCP as the labeler would for other types of device modifications.

- In the draft guidance, FDA states: "under section 513(f)(5), for devices subject to 510(k), FDA may withhold a substantial equivalence determination if FDA finds that there is a substantial likelihood that the failure to comply with QSR will potentially present a serious risk to human health. Thus, consistent with sections 515C(b)(2) and 513(f)(5) of the FD&C Act, FDA may under certain case-by-case circumstances withhold clearance of a PCCP submitted in a 510(k) based on findings in the regulatory history of the manufacturer that demonstrate failure to comply with QSR."[7] CHPA requests that FDA: (1) confirm that this language is intended to reflect only that the existing standard for withholding substantial equivalence determinations applies to FDA's clearance of a PCCP as part of a 510(k) submission; and (2) clarify that the "certain case-by-case circumstances" in which FDA may withhold clearance of a PCCP based on prior failures to comply with QSR are limited to when FDA makes a specific finding

[6] Draft Guidance at 29.

[7] Draft Guidance at 11.

that there is a substantial likelihood that the failure to comply with the QSR will potentially present a serious risk to human health.

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CHPA appreciates the opportunity to provide suggestions to the Agency on the Draft Guidance and the Agency's approach to pre-determined change control plans. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully Submitted,

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