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April 4, 2025

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

Re: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; 90 *Fed. Reg*. 1154-1156, Docket No. FDA-2024-D-4488

Dear Sir or Madam:

The Consumer Healthcare Products Association ("CHPA")[1] submits these comments on the U.S. Food and Drug Administration's (FDA's or Agency's) "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff" ("Draft Guidance").[2] The Draft Guidance was announced in the January 7, 2025, *Federal Register*[3] (90 *Fed. Reg*. 1154-1156; Docket No: FDA-2024-D-4488).

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, OTC medical devices, and dietary supplements. For more than 144 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 use of artificial intelligence (AI)-enabled medical devices will continue to evolve rapidly. It will be critical for FDA to provide a regulatory framework for this technology, including with respect to the information required in regulatory submissions, that is risk-based and scientifically sound while protecting public health. However, this framework should also be flexible enough to allow for innovative, new uses of AI in FDA-regulated device software functions that will certainly be developed in the

[1] 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 Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff. Accessed from https://www.fda.gov/media/184856/download on February 19, 2025.
[3] 90 *Federal Register* 1154-1156; Docket No. FDA-2024-D-4488. Accessed from https://www.govinfo.gov/content/pkg/FR-2025-01-07/pdf/2024-31543.pdf on February 11, 2025.

coming years. By establishing clear and appropriate criteria for premarket submissions and lifecycle management that are also not unduly rigid, FDA will facilitate the development of innovative AI-enabled devices by sponsors[4] while protecting public health.

CHPA is pleased that this draft guidance reflects best practices for the development of AI-based device software. However, we offer the following suggestions and requests for the Agency's consideration as it works to finalize the guidance.

Recommendation 1: The final version of the guidance should explicitly state that the expectations for device labeling content, specific documentation (*e.g.,* of data management practices) and device performance monitoring plans apply prospectively, not to devices that have already received Agency clearance or approval or to medical devices that are 510-(k)-exempt (and are typically not subject to premarket review).

Recommended revision to Section I. Introduction

Original Text from Draft Guidance (Lines 115-117)

This guidance provides recommendations on the contents of marketing submissions for devices that include AI-enabled device software functions including documentation and information that will support FDA's review.

CHPA Proposed Text

This guidance provides recommendations on the contents of marketing submissions for devices that include AI-enabled device software functions including documentation and information that will support FDA's review. *The recommendations outlined in this guidance do not apply to 510(k)-exempt medical devices or to any device that has received FDA clearance or approval prior to issuance of the final version of this guidance.*[5]

Additional feedback from CHPA

The guidance recommendations should apply prospectively only, not to products that have already received Agency clearance or approval. Manufacturers should not be expected to modify their documentation or labeling for cleared or

[4] Unless otherwise stated, for the purpose of these comments, sponsor and manufacturer are used interchangeably.

[5] Comments refer only to those aspects of the Draft Guidance where CHPA has suggested revisions. CHPA is not submitting comments on elements of the Draft Guidance not listed herein. Italicized text in blue (*e.g., sample text*) reflects revisions recommended by industry. Text with double strikethrough (*e.g.,* sample text) reflects text recommended for deletion.

approved devices unless and until there is a modification that would necessitate a new premarket submission to the Agency.

CHPA acknowledges that additional documentation, as outlined in the final guidance once issued, may be warranted in premarket submissions for device modifications depending on the type(s) of changes that a sponsor implements for a product that received clearance or approval prior to the issuance of this guidance. For changes that relate to the AI algorithm or AI-related labeling, CHPA agrees that information as outlined in the Draft Guidance should be submitted in the premarket submission for those changes. But for other types of changes that may be unrelated to the AI algorithm, such as cybersecurity-related updates, the sponsor should not be required to resubmit information under the Draft Guidance for aspects of the device that remain unchanged from the prior approval or clearance.

Recommendation 2: The final version of the guidance should explicitly state that sponsors are only expected to provide information or data relevant to the proposed product that is the subject of the regulatory submission.

Recommended revision to Section II. Scope:

Original Text from Draft Guidance (Lines 194-198)

In some cases, this guidance highlights recommendations from other guidances in order to assist manufacturers with applying those recommendations to AI-enabled devices. The inclusion of certain recommendations in this guidance does not negate applicable recommendations in other guidances that may not be included. This guidance should be considered in the context of the FD&C Act, its implementing regulations, and other guidance documents.

CHPA Proposed Text

In some cases, this guidance highlights recommendations from other guidances in order to assist manufacturers with applying those recommendations to AI-enabled devices. The inclusion of certain recommendations in this guidance does not negate applicable recommendations in other guidances that may not be included. This guidance should be considered in the context of the FD&C Act, its implementing regulations, and other guidance documents. *Sponsors should assess which recommendations in the guidance are applicable to their AI-enabled device software function(s) and incorporate only those elements relevant to their regulatory submissions.*

Additional feedback from CHPA

CHPA members applaud FDA for providing comprehensive guidance to assist manufacturers whose marketing submissions for devices include AI-enabled device software functions to support the regulatory review process. However, the final guidance should be clear that only information relevant to the sponsor's specific product is expected to be addressed in the regulatory submission. A manufacturer should rely on its internal knowledge and expertise of both the product and AI-algorithm to determine which elements of the guidance apply. As an example, see CHPA's recommendation below regarding labeling for AI-enabled devices (Recommendation 3).

Recommendation 3: The final guidance should reflect that the content of AI-enabled device labeling should be appropriate for the intended primary end-user.

Recommended revision to Section IV. B. Labeling - Patient and Caregiver Information

Original Text from Draft Guidance (Lines 658-666)

For AI-enabled devices intended for use by patients or caregivers, manufacturers should provide labeling material that is designed for patients and caregivers describing the instructions for use, the device's indication, intended use, risks, and limitations. Patients and caregivers are considered users if they will operate the device, interpret the outcome, or make decisions based on the outcome, even if they are not the only user or the primary operator of the device. This material should be at an appropriate reading level for the intended audience. If patient and caregiver-specific material is not provided, sponsors should provide an explanation of how patients and caregivers will understand how to use the device, including how to make decisions about whether to use the device and how to use the output of the device.

CHPA Proposed Text

For AI-enabled devices intended for use by patients or caregivers, manufacturers should provide labeling material that is designed for patients and caregivers describing the instructions for use, the device's indication, intended use, risks, and limitations. Patients and caregivers are considered users if they will operate the device, interpret the outcome, or make decisions based on the outcome, even if they are not the only user or the primary operator of the device. This material should be at an appropriate reading level for the intended audience. *The types of information and level of detail required for labeling of medical devices intended to be used by healthcare professionals may differ from that for labeling used by patients or caregivers. Likewise, appropriate information for inclusion in device labeling necessary to ensure safe and effective use of the device may differ for devices that*

must be prescribed by a healthcare professional and for over-the-counter devices. Sponsors are expected to submit only the relevant information types outlined in Section B. If patient and caregiver-specific material is not provided, sponsors should provide an explanation of how patients and caregivers will understand how to use the device, including how to make decisions about whether to use the device and how to use the output of the device.

Based on their expertise, sponsors should evaluate the comprehension of consumers and caregivers as the end-users of devices intended only for consumer use, and not for other potential users (e.g., healthcare professionals, installers, and other operators). Although conducting a label comprehension study[6] may be one method to assess a consumer's or caregiver's comprehension level, it is not required. A sponsor may use other scientifically-valid methods to evaluate comprehension if most appropriate for its development program.

Additional feedback from CHPA

CHPA appreciates FDA's acknowledgment that labeling for devices intended for use by patients or caregivers may differ from labeling for devices intended for use by healthcare professionals. CHPA seeks further clarification about which of the recommended labeling elements described in the Draft Guidance are applicable for devices intended to be used by patients, caregivers, or other lay persons as compared to devices intended for use by healthcare professionals. For example, the Draft Guidance recommends that labeling include detailed information about model inputs, such as information on necessary system configuration for systems incorporating inputs from an electronic interface, and detailed information about the model development data. However, it is not clear that this level of detail will be helpful to patients or caregivers in understanding the use of the device or necessary for safe and effective use of over-the-counter devices. Therefore, CHPA requests that FDA further clarify that not all of the information types listed in the guidance would be expected to be included in labeling for OTC AI-enabled devices.

Furthermore, we ask FDA to specify the accessible format(s) that labeling should be made available for the intended audiences. CHPA recognizes that, according to existing regulations, products must have static (*i.e.,* paper) labeling. However, we strongly recommend that FDA allow manufacturers to also provide electronic labeling (*i.e.,* dynamic product labeling) to consumers as the company deems useful or necessary.

[6] FDA Guidance for Industry Label Comprehension Studies for Nonprescription Drug Products (August 2010). Accessed from https://www.fda.gov/media/75626/download on February 23, 2025.

Recommendation 4: The FDA should explicitly address protections for proprietary information in the guidance to ensure that sponsors can comply with transparency requirements without disclosing trade secrets or confidential commercial information. We recommend that FDA provide clear mechanisms for redacting or summarizing AI model details, including dataset specifics and algorithmic methodologies, while still meeting regulatory oversight requirements.

Recommendation 5: We agree with the Agency's stated intention to use a risk-based approach for determining specific testing and applicable recommendations to support marketing submissions for AI-enabled devices (see lines 214-215 of the Draft Guidance). CHPA recommends that FDA further clarify which recommendations of the Draft Guidance would not be expected for lower-risk devices, such as OTC medical devices (which are typically regulated as Class I and certain Class II medical devices).

In summary, CHPA appreciates the opportunity to provide comments to FDA on its draft guidance "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations." We hope to see these recommendations incorporated into the final version of the guidance when issued and are available to answer any questions during the Agency's review of the docket submissions.

Respectfully Submitted,

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