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Office of Operations Food and Drug Administration Three White Flint North 11601 Landsdown St. North Bethesda, MD 20852

Re: Docket No. FDA-2023-N-0155

The American Heart Association (AHA) appreciates the opportunity to provide feedback on the proposed quantitative research on front-of-package labeling on packaged foods.

AHA strongly supports the development of a front-of-package (FOP) labeling system. A comprehensive, nutrient-specific FOP system that appears on all foods and beverages, not just a select few, will help consumers make healthier choices and better understand the nutritional contribution of their foods and beverages. A mandatory FOP system will also prompt manufacturers to innovate, reformulate, and produce healthier offerings.

We appreciate the Food and Drug Administration's (FDA) efforts to develop a FOP system that is based on the best available science and consumer research. The FDA's literature review, the 2022 focus groups, and this proposed quantitative research study will help the agency identify the FOP system that best communicates important nutrition information to consumers quickly, easily, and accurately. We encourage the FDA to move forward with this consumer research and we look forward to learning the results.

One area we recommend FDA clarify, however, is whether the agency intends to include calorie information in the FOP system. Many of the FOP schemes tested during the 2022 focus groups included calorie information (example below):



But calorie information is no longer included as part of the FOP schemes that will be tested in this latest round of consumer research. According to the Federal Register notice:

FDA declines to add calories to the schemes we are testing or test a calorie-only scheme. Our regulations, at 21 CFR 101.9(d)(1)(iii), require the Nutrition Facts label to display calorie information with increased prominence, relative to other information, in order to draw consumer attention. At this point, for the purposes of this experimental study, we believe that consumers have adequate access to calorie information, while the purpose of our research on FOP is to determine the usefulness of providing consumers with additional factual context for making healthy food selections.¹

It is unclear from this text why FDA chose to remove the calorie information from the latest round of FOP schemes. The explanation – that calories are displayed prominently on the Nutrition Facts label giving consumers "adequate access" to calorie information – would also have applied when FDA tested the earlier calorie-included FOP schemes; it is unclear what changed. It is also unclear if FDA is only removing calorie information from this round of consumer testing, or if FDA has already decided calorie information will not be part of the FOP system it ultimately adopts. We encourage the FDA to clarify and communicate its thinking on this issue.

Thank you again for the opportunity to comment and for your commitment to developing an evidence-based FOP system.

Sincerely,

Mark Schoeberl

Executive Vice President, Advocacy

¹ 88 FR at 39,263.