July 6, 2021

Janet Woodcock, MD Acting Commissioner Food and Drug Administration Dockets Management Staff (HFA-305) 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852



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RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Foods [Docket No. FDA-2021-N-0336]

Dear Dr. Woodcock:

The Academy of Nutrition and Dietetics (the "Academy") appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) related to its information collection for "Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim 'Healthy' on Packaged Foods" (Docket No. FDA-2021-N-0336). Representing more than 112,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to accelerating improvements in global health and well-being through food and nutrition. Our members work in a variety of clinical and community settings across the continuum of care and work with industry and consumers to develop and effectively utilize product labels that encourage individuals to make healthy food choices.

The Academy supports the proposed information collection of three quantitative consumer research studies consisting of an experimental study and two surveys to assist the FDA in understanding how consumers perceive a variety of symbols intended to convey that a product labeled with such symbols meets the FDA's requirements for using the implied nutrient content claim declaring it is "healthy." We look forward to analyzing forthcoming research results in advance of the FDA's promulgation of a new definition for "healthy," because we recognize there is no benefit to the consumer and no positive impact on health from a nutrient content claim unless it is widely disseminated, understood, and used.

## A. Consumer Research Is Needed and Will Have Practical Utility

The Academy's April 26, 2017 comments to FDA regarding the definition of the "healthy" nutrient content claim¹ emphasized the need to conduct substantial consumer research prior to proposing a new definition to better understand both the current environment of

<sup>&</sup>lt;sup>1</sup> Academy Comments to FDA re the Definition of the "Healthy" Nutrient Content Claim. Academy of Nutrition and Dietetics eatrightpro.org website. Available at <a href="https://www.eatrightpro.org/news-center/on-the-pulse-of-public-policy/regulatory-comments/academy-comments-to-fda-re-the-definition-of-the-healthy-nutrient-content-claim">https://www.eatrightpro.org/news-center/on-the-pulse-of-public-policy/regulatory-comments/academy-comments-to-fda-re-the-definition-of-the-healthy-nutrient-content-claim</a>. Accessed July 6, 2021.

consumer understanding and engagement and to identify whether the types of tools, rules and educational initiatives being considered are likely to accomplish their goals. The consumer research proposed in this information collection helps to accomplish these purposes and is thus not only necessary for the proper performance of FDA's functions but will have practical utility for the FDA and other stakeholders.

We reiterate relevant elements of our April 26, 2017 comments:

The Academy continues to support the Food and Drug Administration-approved health claims on food labels "when based on rigorous scientific substantiation." More specifically, "[t]ools designed to help individuals choose and consume nutrient-dense foods should be grounded in science, validated against objective measures of diet quality, and most importantly, be able to effectively translate recommendations into actionable strategies." We are optimistic that if a proposed definition of "healthy" meets the necessary scientific standards and its meaning is properly and sufficiently understood by the public, the "healthy" label could be an effective tool for enhancing consumers' ability to make improved eating choices.<sup>2</sup>

## B. Ways to Enhance the Quality, Utility, and Clarity of the Information Collected

The request for public comment indicates that the graphic symbols being tested in the proposed information collection are intended to "help consumers identify packaged food products that meet FDA's definition of 'healthy.'" Notably, although the symbols available in Docket No. FDA-2021-N-0336 tend to indicate some alignment between the FDA and the term "healthy" (e.g., through an explicit or subtle checkmark or other associative visual indicator) and could thus help customers identify products the FDA deems "healthy," the symbols do not provide consumers with substantive information about the underlying definition they could use to make informed choices.

We recognize the significant value of labeling and the use of symbols that provide succinct and easily understandable and useable information and note it is not the inherent role of a symbol to explicitly convey each of the details of the claim it represents. However, as the Academy emphasized in one of its principles for labeling initiatives adopted in 2014 to guide our comments and policy stances, "labels should help to provide understanding about the healthfulness of overall food rather than a focus on particular nutrients" because it provides context and more accurately reflects how people eat and how they think about eating. We encourage the FDA to clarify how the symbols provide this important context.

As this proposed information collection assessing consumers' understanding that the symbol meets the FDA's definition of "healthy" will be conducted *prior* to the FDA

<sup>&</sup>lt;sup>2</sup> *Ibid.*, quoting Crowe KM, Francis C. Position of the academy of nutrition and dietetics: functional foods. J Acad Nutr Diet. 2013;113(8):1096-103 (emphasis added) and Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. J Acad Nutr Diet. 2016;116(9):1473-9.

establishing its new definition of healthy, consumers will not be able to ascertain the actual meaning of the symbol (since that symbol—if used now—would mean something different than the symbol used after the FDA revises the definition of "healthy." Thus, we believe it is important for the information collection to gauge more than just mere compliance with an FDA definition at any given time but also to qualitatively gauge how consumers perceive the symbol as helping them consume a healthy dietary pattern.

The healthfulness of a food in a dietary pattern relates to the portion-size of the food, its nutrient density, and its composition in terms of nutrients of concern, not simply the presence of absolute amounts of a single nutrient. As we noted in our earlier comments to the FDA on the definition of "healthy," we remain concerned that the term "healthy" on the label as an implied nutrient content claim has the potential to cause consumer confusion if it implies that a single food should meet all dietary needs. Given the possibility that only a very restricted subset of nutrients will be relevant in determining whether a particular packaged food product is "healthy," the FDA should also study whether designation of some products as "healthy" leads consumers to deem unlabeled products "unhealthy" with associated negative feelings.

Given the FDA's responsibility to determine whether consumer understandings of the term "healthy" comport with its legally established meaning, we encourage specifically asking respondents about their understandings of the term's definition and how foods classified as "healthy" can help them adopt healthy dietary patterns. We also respectfully suggest the FDA considers how to convey the meaning, use, and changing definition of the term "healthy" as it continues to exercise its responsibility for coordinating the education of consumers given there will not likely be a readily available definition on the packages themselves.

## C. Conclusion

The Academy appreciates the opportunity to submit comments related to the information collection for "Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim 'Healthy' on Packaged Foods" and supports the FDA's important work on the implied nutrient content claim "healthy" and its broader Nutrition Innovation Strategy. Please contact either Jeanne Blankenship by telephone at 312-899-1730 or by email at <a href="mailto:jblankenship@eatright.org">jblankenship@eatright.org</a> or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at <a href="mailto:jblankenship@eatright.org">jblankenship@eatright.org</a> or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at <a href="mailto:jblankenship@eatright.org">jblankenship@eatright.org</a> with any questions or requests for additional information; we would welcome the opportunity to provide whatever assistance we can in this endeavor.

Sincerely,

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