United States Food and Drug Administration

Quantitative Research on a Voluntary Symbol
Depicting the Nutrient Content Claim "Healthy" on Packaged Foods

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations and programs. Section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits the use of label and labeling claims that characterize the level of a nutrient in a food only if the claims are made in accordance with FDA's regulations. Such claims are referred to as "nutrient content claims." We have issued regulations under section 403(r)(1)(A) of the FD&C Act defining "implied nutrient content claims" as those that imply that a food, because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations ("Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms," 58 FR 2302 at 2374, January 6, 1993). We have found that a claim that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health (58 FR 2302 at 2375). In 1994, we issued a definition of "healthy" as an implied nutrient content claim (59 FR 24232, May 10, 1994); the regulation is codified at 21 CFR 101.65(d)(2).

In 2018, FDA announced our Nutrition Innovation Strategy, outlining key priorities the agency intended to pursue to reduce the burden of chronic disease through improved nutrition and advance its public health mission. As one element of the Strategy we are exploring the development of a graphic symbol to help consumers identify packaged food products that meet FDA's definition of "healthy." The symbol would be a graphic representation of the nutrient content claim "healthy" and, like the implied nutrient content claim "healthy", would be voluntary for packaged food companies; companies could use the symbol on their food products if the products meet the FDA definition of "healthy."

In 2019 and 2020, FDA conducted a systematic review of the literature on front-of-package nutrition-related symbols. The global literature take-aways are:

- A FOP rating system or symbol can help consumers identify and select healthy foods;
- Consumers generally prefer simple labels (such as the ones using a summary system);

- There is limited research on: (1) which type of summary system works best, and; (2) whether consumers' use of summary systems result in healthier diets;
- Some manufacturers have reformulated products following the implementation of FOP nutrition symbols; there is some evidence of increased sales of products bearing a FOP symbol; and
- Institutional endorsement of logos may be related to greater confidence in the label.

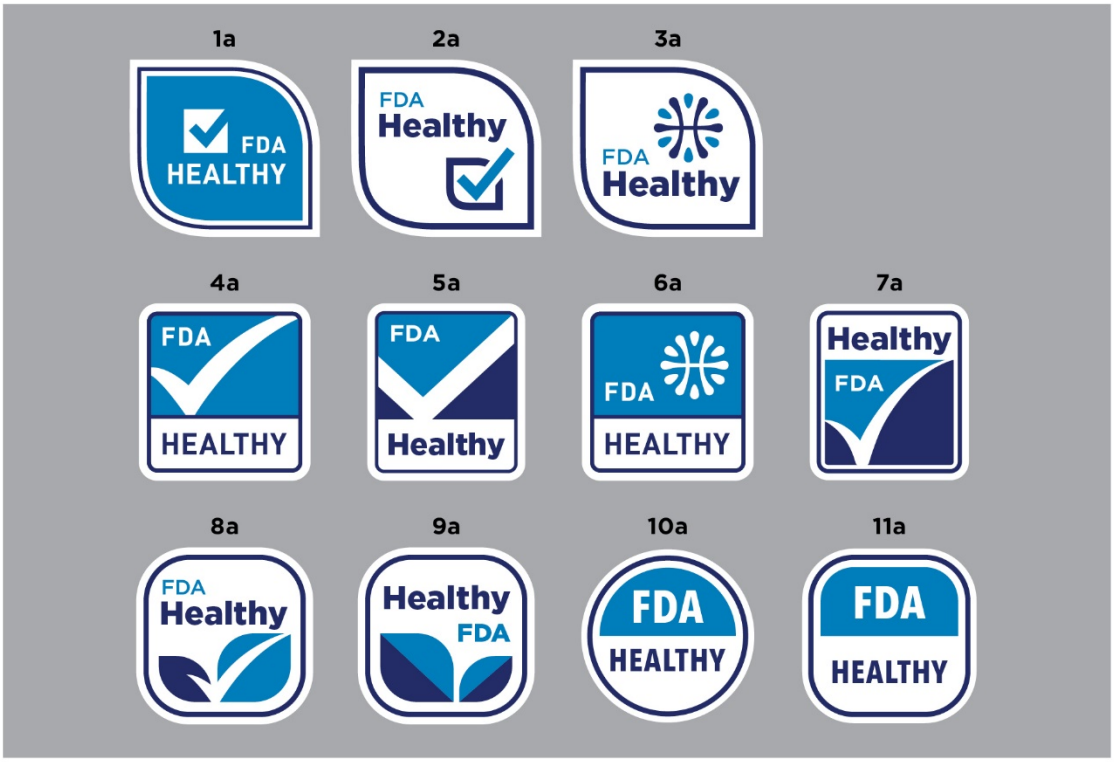
FDA also held three sets of eight focus groups to get consumer reaction, first to symbol prototypes and then to possible FDA "healthy" symbols, with modifications made to the symbols between each set of groups. The overall takeaways from the focus groups were that participants were favorably disposed to the idea of FDA creating a "healthy" front-of-package symbol. Because the symbol would be coming from a trustworthy organization like FDA, participants said shopping for healthy food items would be easier and quicker. Participants agreed that "FDA" would need to be displayed on whatever symbol is ultimately developed so that consumers can distinguish FDA's designation from a marketing effort by the manufacturer.

Certain symbol design elements resonated better with the focus group participant than did others; e.g., rounded squares and checkmarks. Other elements engendered responses that FDA did not desire. For example, symbols containing leaves or the color green invoked environmental issues, "apples" invoked school.

Following the third set of focus groups, the contracting design firm and FDA continued revising the symbols that had been tested in the focus groups, settling on the symbols shown in Figure 1 as the set with which to begin the quantitative research.

We therefore request OMB approval of this collection of information as discussed in this supporting statement.

Figure 1. Draft "Healthy" Symbols



2. Purpose and Use of the Information Collection

As part of our efforts to promote public health, we intend to conduct two consecutive quantitative research studies—a survey (Study 1) and an experimental study (Study 2) to explore consumer responses to the draft FOP symbols that companies could voluntarily use on a food product as a graphic representation of the nutrient content claim "healthy." If research results suggest the need, the symbols will be fine-tuned following the survey and again following the experimental study.

Study 1 will use non-probability survey methods, using a web-based panel to draw a sample of 2,000 U.S. adults ages 18 and older who self-identify as primary food shoppers. The sample will be balanced to the demographics of the U.S. population. The survey instrument will focus on clarity, relevance, and appeal of the symbols in Figure 1.

Study 2 will be a controlled, randomized experiment that will use a 15-minute web-based questionnaire to collect information from 5,000 U.S. adult members of an online consumer panel. Conditions for Study 2 will be: (1) A set of draft FOP symbols, including "no-symbol" controls; (2) three types of mock food products (i.e., a breakfast cereal, a frozen meal, and a canned soup); (3) a "no-information" condition where no explanation of the symbol is provided; and (4) a Uniform Resource Locator (URL) condition, in which a URL is tested alongside the symbol. Each participant in Study 2 will be randomly assigned to a condition, which will include viewing a label image and responding to various measures of the symbol's effectiveness. Measures of response in

the experiment will include product perceptions (e.g., healthfulness and contribution to a healthy diet), label perceptions (e.g., believability, trustworthiness, message effects), and purchase/choice questions. The instrument will also collect information from participants about their history of purchasing or consuming similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status; and demographic characteristics.

The studies are part of FDA's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. We intend to use the results to inform our continued exploration of a symbol manufacturers could voluntarily use to represent the nutrient content claim "healthy" on the food label. We will not use the results to develop population estimates.

Experiment. Prior to administering the experimental study, the FDA will conduct nine cognitive interviews with English-speaking adults to identify potential response error caused by the questionnaire and study materials. A pre-test with 180 adults will also be conducted prior to administering the experimental study. It is expected that there will be minor adjustments to the study materials following the cognitive interviews and the pretests.

The study will use a 15-minute Web-based questionnaire to collect information from 5,000 English-speaking adult members of an online consumer panel maintained by a contractor. Researchers will endeavor to collect samples that reflect the U.S. Census on gender, education, age, and ethnicity/race.

The research questions to be answered by the experimental study are:

1. Which symbol(s)…
    - (a) communicates that the product meets FDA's definition of healthy?
    - (b) communicates that the food is a healthy choice?
    - (c) influences product purchase?
    - (d) reflects perceptions of greater trust and believability?
    - (e) gets consumer attention?
    - (f) elicits a positive affect?
    - (g) affects motivation to consume the foods?
2. How does exposure to the FDA Healthy definition (via an education piece) affect outcome measures (from #1 above)?
3. How does inclusion of a URL affect outcome measures?
4. How does the checkmark versus a checkmark-alternative affect outcome measures?
5. Does the product type mediate the effect of the symbol on selected outcome measures (cereal vs. frozen meal vs. soup]?
6. How do demographics, health status, perceptions of product healthfulness, motivation (and other covariates) mediate the symbol outcome measures?

Conditions for the experimental study will be: (1) a set of draft symbols, including "no-symbol" controls; (2) three types of mock food products (i.e., a breakfast cereal, a frozen meal, and a canned soup); (3) a "no-information" condition where no explanation of the

symbol is provided; and (4) a URL condition, in which a URL is tested alongside the symbol. Participants will be randomly assigned to view a food label image and answer questions about their perceptions and reactions to the label. Product perceptions (e.g., healthiness, and contribution to a healthy diet), label perceptions (e.g., believability and trustworthiness), and purchase/choice questions will constitute the measures of response in the experiment. To help understand the data, the instrument will also collect information about participants' background, such as purchase and consumption of similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status and demographic characteristics.

3. Use of Improved Information Technology and Burden Reduction

FDA intends to use only electronic means to fulfill the agency's request.

The research will use only web-based consumer panels and questionnaires. Web-based questionnaires not only reduce the burden on participants, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, web-based data collections are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

No comparable data have been collected by any other entities because the exploration of an FDA-sponsored symbol to depict the Nutrient Content Claim "Healthy" is specific to the interests of the FDA. The experimental study and two surveys proposed here will provide valuable information about the effectiveness of a "Healthy" symbol and consumers' reactions to them.

As discussed in Item 1, FDA began exploring developing a "Healthy" symbol by conducting a systematic review of the scientific and grey literature on FOP nutrition symbols. Results of the literature review revealed that FOP symbols have been extensively studied and some large-scale literature reviews on FOP nutrition systems and symbols had been conducted. In particular, the Institute of Medicine conducted a two-phased literature review on FOP symbols (Refs. 1 and 2) and concluded that they are beneficial to consumers and that simple systems or symbols are preferred. FDA began its specific exploration using the findings from the literature to that date and is informed by a continued monitoring of the literature throughout the research process.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

If this information is not collected, FDA will not know how consumers respond to measures of the effectiveness of- nor evaluative feedback on- an FDA-developed symbol for depicting the nutrient content claim "Healthy" which manufacturers can voluntarily use on the food label if their product meets the FDA definition for using the nutrient content claim.

The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require participants to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The experimental study will produce results that can be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is: (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of May 7, 2021 (86 FR 24629), FDA published a 60-day notice requesting public comment on the proposed information collection. We received 43 comments, 27 of which were PRA-related. The remaining comments were non-responsive to the four PRA topics, and so we will not address them in this document. A. *Comments regarding the necessity and practical utility of the information being collected and FDA response*Several comments addressed the necessity and practical utility of collecting information on a voluntary symbol depicting the nutrient content claim "healthy" on packaged foods.

(Comment 1) Some comments supported FDA's proposed collection of information through the three proposed quantitative consumer research studies. Some comments expressly supported FDA's end research goal of enabling consumers to make informed dietary choices and construct healthful diets. Some supported FDA's intention to understand consumer responses to draft FOP symbols and gather data and other information to inform our thinking on a "healthy" symbol. Many comments indicated the importance of conducting this research before taking regulatory action on any symbol. Some comments supported conducting the research in conjunction with development of a proposed rule that would update the definition of "healthy" on food packages.

Other comments opposed FDA research on a "healthy" symbol. Some of these comments suggested the research is unnecessary, claiming that a single food is not "healthy" or "unhealthy," that overall diet matters more than individual foods, or that symbols are industry marketing. A few comments suggested a "healthy" symbol could be particularly misleading to, or misinterpreted by, people who are experiencing eating disorders. Some comments also questioned whether a "healthy" symbol would: (1) have a positive and meaningful impact on improving health; or (2) lead consumers to overconsume foods bearing the symbol.

(Response 1) We intend to conduct this research now, in conjunction with further work on updating our definition of the claim "healthy" and before taking regulatory action on any symbol. Our intended research will help us better understand how consumers might respond to and use a graphic symbol to identify packaged food products that meet our definition of "healthy." This research will help address many points raised in the comments, such as how consumers might react to and understand a "healthy" symbol and misinterpretations they may have.

While we agree that there are some symbols that may be used exclusively for industry marketing, companies could use any FDA "healthy" symbol we develop and finalize only when the product displaying the symbol meets FDA's regulatory definition of "healthy." This could help consumers make more informed dietary choices and construct healthful diets. The comments claiming that a single food is not "healthy" or "unhealthy" and that overall diet matters more than individual foods are commenting on the "healthy" claim itself, which we do not intend to test in this research. Rather, we intend to test consumer reactions to symbols that could be a graphic representation of the claim. Nonetheless, we note that a "healthy" symbol, such as the ones FDA is exploring in our research, could help consumers choose food products, *as part of their overall diet*, that meet FDA's regulatory definition of "healthy." The research is not designed to study long-term health effects or consumer consumption patterns. We reiterate that this research is about graphical representations of the nutrient content claim "healthy" – in other words, we intend to study only the symbol, not the claim itself. Depending on the results of this data collection, we may decide to test additional symbols or revise our current symbols.

(Comment 2) Many comments expressed a preference for conducting the research after we revise our regulatory definition of "healthy," as they wondered whether the definition of the claim could influence both the design and consumer understanding of the symbol. Some expressed concern that testing a symbol without clearly communicating what the symbol means could lead to ambiguous results. One comment expressed concern that, by conducting testing only on the symbols in the notice, we would not consider testing any other symbols in the future. A few comments contended that FDA's testing would be invalid if the mock products used in testing do not meet FDA's updated "healthy" definition.

(Response 2) FDA has an existing definition for the claim "healthy," and in the *Federal Register* of September 28, 2016, we announced our intent to exercise enforcement

discretion around some criteria for the claim (see "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry," 81 FR 66487 at 66527). However, as part of this data collection, we have included experimental conditions in which participants will read general information outlining the use of the claim "healthy" only for purposes of this study. This will help us better understand how consumers might respond to the symbols we are proposing to test if participants understand a "healthy" definition, even if not necessarily an updated definition. While the symbol is intended to represent the nutrient content claim "healthy," our research on the symbol is not dependent on specific criteria for "healthy." We are researching general consumer perceptions and impressions of the symbols themselves, not the definition that may underly those symbols, and as such, we do not need to wait until we have a final, updated regulatory definition of "healthy" before conducting this research. Moreover, the symbols being tested would not need to be modified with a changing definition of "healthy;" the symbol would remain a simple graphic representation of the "healthy" claim.

Regarding the claim that our testing would be invalid if the mock products used in testing do not meet FDA's updated "healthy" definition, our mock products represent broad and basic food categories. They include foods such as vegetables and whole grains with limited nutrients of concern (e.g., sodium or saturated fat) that would meet our current definition of "healthy" and would help consumers build a diet consistent with the *Dietary Guidelines for Americans, 2020-2025*.

B. Comments regarding the accuracy of our burden estimates, including the validity of the methodology and assumptions used, and FDA response

Many comments discussed the accuracy of FDA's estimate of the burden for this information collection, including the validity of FDA's methodology and the assumptions used.

(Comment 3) Several comments alleged that we provided limited details about our proposed research studies and encouraged us to publish additional information on the proposed scope and methodology of our consumer research to allow for more comprehensive input from experts in the field of consumer research. One comment suggested we "pre-register" details of the proposed studies on AsPredicted.org or ClinicalTrials.gov so that stakeholders could better understand the primary outcome of the research, hypotheses, analytic plan, and power analysis used.

(Response 3) We described the research in the 60-day notice, providing information on research design, measures, sampling, and sample size. Many comments substantively addressed these issues, and so we believe there was enough information about the studies in the 60-day notice for the public – including consumer researchers – to comment on the research.

We specified in the 60-day notice that we intend to use the results to inform our continued exploration of a symbol manufacturers could voluntarily use to represent the

nutrient content claim "healthy" on the food label (86 FR 24629 at 24631). The comment did not provide sufficient information regarding additional details that it believed necessary for stakeholders to better understand this primary outcome, hypotheses, analytic plan, and power analysis used, and it did not explain what additional details might be available via pre-registration that would not be available in our *Federal Register* notices. Therefore, we are unable to provide those details here, and we also decline to pre-register our studies.

(Comment 4) One comment questioned the ordering of the quantitative research, asking why the experimental studies come before the surveys. Other comments suggested we use the two surveys to test draft symbols first to narrow down options and test the "final" symbols in the experiment, or to conduct preliminary research to narrow the options for the experiment.

(Response 4) We conducted several phases of qualitative research to solicit input from consumers, allowing us to evaluate symbol prototypes and design elements to learn what resonated with consumers. Through that process we narrowed our draft symbol options. After considering public comments, we have reconsidered the order of the research, and plan to conduct one survey with a larger sample size (instead of two surveys with smaller sample sizes each) before the experimental study. In other words, we will reorder the studies and combine the two surveys into one, which will allow us to test all symbols in a single survey. While our proposed information collection is intended to help us better understand how consumers might respond to and use a graphic symbol that indicates packaged food products meet FDA's definition of "healthy," and all the draft symbols we proposed to test would allow us to do that, we expect conducting a single survey first will help us further revise and narrow down the set of symbols.

(Comment 5) One comment suggested we use a more naturalistic study environment, such as an online store setting, instead of using images.

(Response 5) Online store settings and other naturalistic study environments have been successfully employed in some studies on food labeling effects. One advantage of employing such naturalistic study environments is that they more closely reflect participants' actual shopping experience. However, there are substantial additional costs associated with using such research settings, and results in these settings generally do not differ appreciably from results garnered through the simple random-assignment-to-condition design that we proposed. Therefore, we decline to change our study environment.

(Comment 6) One comment suggested that FDA separate different aspects of the symbols to isolate consumer perceptions of the word "healthy," the graphic itself, and the graphic accompanied by the word "FDA." One comment suggested that FDA should test each symbol with and without "FDA."

(Response 6) Separating each aspect of the symbols for our testing would increase the number of conditions exponentially, making the design impractical. We instead elected

to use a full factorial design with simple random assignment to condition, to give us results on the performance of the various symbol designs. Using random assignment to condition, we may be able to eliminate some symbols without needing to test particular attributes in any one symbol. We may consider alternate study designs when we have a narrower set of symbols.

One finding of our literature review was that institutional endorsement may be related to greater confidence in the symbol. Our focus group research affirmed that participants regarded symbols with "FDA" as more trustworthy than symbols without "FDA." Therefore, for the intended research, we are testing draft symbols with "FDA." We may consider additional research on this point depending on the results.

(Comment 7) One comment recommended using images of real food products in the experimental studies instead of using mock product images.

(Response 7) FDA does not agree with the recommendation to use images of real products in the experimental studies. Mock images remove the potential for brand biases, a source of response error that has been demonstrated to affect the way individuals answer survey questions. Mock food product labels psychologically remove the salience of branded product informational cues present in the retrieval stage of the response process (Refs. 3 and 4). Additionally, the mock product labels we designed are visually similar to labels consumers could expect to see in stores for each given product category. We confirmed this assertion in our qualitative testing by noting that participants perceived the mock product labels as ones with which they were unfamiliar, but which were plausible for the food product depicted.

(Comment 8) One comment suggested that we should assess "multi-tier symbols" in addition to the symbols we intend to test. The comment suggested that multi-tier symbols are those that use, for example, an increasing number of stars to indicate to the consumer that a choice is "good," "better," or "best." The comment argued that a multi-tiered approach could encourage consumers to make incremental improvements in their diets, enable manufacturers to reformulate products to meet the initial tier of the system, and increase the number of foods with at least some healthful benefits that could carry a symbol.

Another comment suggested that FDA consider a symbol that warns consumers about high levels of unhealthy nutrients. Another comment asserted that we should also test what it suggested were more neutral FOP labels, such as traffic lights, nutrition scoring symbols, and warning symbols, to better assist consumers in making healthy choices and motivate manufacturers to make healthier foods.

(Response 8) For the purpose of this study, we are testing only symbols that would be a graphic representation of the nutrient content claim "healthy" – a food that could bear that claim could also bear the symbol. FDA's systematic literature review suggested that a summary indicator – the type we are proposing to test – would have the greatest utility to depict the "healthy" claim to a broad array of consumers, especially those with lower

education or lower health literacy. As such, we disagree that we should test other kinds of symbols to depict the nutrient content claim "healthy." We are testing different draft symbol designs based on our literature review and the feedback we collected through our focus group research. Our current study plans are limited to testing summary symbols depicting the nutrient content claim "healthy" to get reactions to design elements and to reduce the current number of symbols under consideration. Because there are no "healthy" tiers in the nutrient content claim, we decline to test a tiered symbol.

(Comment 9) One comment encouraged us to consider testing the "healthy" symbol alongside other current voluntary FOP labels – rather than as the only symbol on a package – to determine the effect of other FOP labels on the efficacy of the "healthy" symbol.

(Response 9) Our studies are designed to test general consumer responses to the symbols presented. Testing additional variables, such as the effect of other packaging elements on the symbols, is outside the scope of this research. We may decide to test "healthy" symbols alongside other FOP symbols in later research depending on the results from this data collection.

(Comment 10) One comment recommended randomizing participants to see subgroups of symbols, claiming it would be an efficient use of resources.

(Response 10) FDA agrees with the recommendation that participants be randomly assigned; however, we disagree with the recommendation to have participants view subgroups of symbols. We plan to randomly assign participants to see a single symbol condition, including product type, information on the definition of healthy, URL/no-URL, and set of symbols. Viewing a single symbol condition precludes the effects of biases that may result from having viewed and responded to questions about one symbol affecting responses about another symbol (Ref. 4). Therefore, even if we might use fewer resources by assigning participants to see subgroups of symbols, the practice would introduce biases and confounds that could make interpreting the results very difficult.

(Comment 11) One comment recommended incorporating time limits for a choice task to better mimic real-life scenarios where consumers have only limited time to shop.

(Response 11) The current experimental study design is random assignment to condition with no "choice task." While time-constraint studies can be useful to test certain variables, our research goal is for the participants to provide thoughtful responses, unaffected by the stress that a time limit could impose.

(Comment 12) A few comments recommended that the studies be adequately powered to enable FDA to do appropriate statistical analysis.

(Response 12) Our studies are designed to have the appropriate statistical power to conduct all necessary statistical analysis. We will test hypotheses related to between-label differences. We will impose no a priori direction of differences, if any (i.e., we

assume all tests are two-tailed). The target sample size (5,000 for the experimental study and 2,000 for the survey) will yield enough observations to provide adequate power to identify 4-way interactions of a medium size (Ref. 5).

(Comment 13) One comment recommended that we test the draft "healthy" symbols in the context of restaurants.

(Response 13) Our research plans include testing symbols solely on packaged foods. Testing "healthy" on a packaged food label versus in a restaurant minimizes the many confounding factors inherent in studying claims in a restaurant environment, such as the enormous variance in size and content of materials used to sell restaurant food. Keeping the studies limited to packaged food labels allows FDA to better isolate various effects of the symbols to strictly test consumer perceptions about the symbols. Additionally, as we noted in response to another comment, we have no reason to believe that adding additional test product categories would change the study outcomes given our goal of testing consumer responses to the symbols.

(Comment 14) Some comments recommended that FDA include more than three mock product types in the experimental studies because of the potential that consumer perceptions of a "healthy" symbol might be different on different products. One comment suggested including a variety of food categories in the studies, while a few other comments recommended including specific product categories, including beverages and fresh produce, so FDA could assess consumer reactions to, or preferences for placement of, a symbol on those products.

(Response 14) FDA disagrees with the recommendation to add more product types to the studies. We are proposing to test "healthy" symbols on a set of mock products that belong to large food categories, with many product types within each category. The broad product categories for those mock products are likely to contain multiple products that currently meet FDA's regulatory definition of "healthy."

For our research, we chose three packaged foods that are commonly consumed and that are clearly distinct food types. The selected products will give us sufficient information on general consumer responses to the symbols to continue development of a proposed "healthy" symbol. We also note that adding any products would increase the scope and cost of the studies while providing limited new information and that the comments provided no evidence that additional test products from other food categories would impact our study outcome.

We decline to include a beverage as one of the mock products. While beverages that meet FDA's definition of "healthy" could bear any "healthy" symbol we finalize, the same is true of any packaged food, and as we explained above, we have no reason to believe that adding additional test product categories would change the study outcomes. We decline to add fresh produce to the studies for the same reasons.

(Comment 15) A few comments recommend comparing foods with a "healthy" symbol and foods that may have healthful attributes but do not meet the regulatory definition of "healthy," to evaluate whether use of the symbol might result in discouraging purchase of foods that have important nutrients but that do not meet the definition of "healthy." Another comment suggested testing a variety of products ("healthier" and "less healthy") for each food product category included in the studies.

(Response 15) The studies are not designed to test purchasing behavior, and so we decline to add mock products for that purpose. Rather, this research is designed to test general consumer responses to the symbols themselves. Additionally, a product could only bear the symbol if it qualified to bear the "healthy" claim itself – the symbol is a graphic representation of the claim – and we are not testing the claim definition or its effects here.

One of the study assumptions is that, like the nutrient content claim "healthy," any food bearing a "healthy" symbol on its label must meet the regulatory definition of "healthy." Therefore, to test consumer responses to the symbols, we do not need to test the ancillary effects of a "healthy" symbol on foods that do not bear the claim. Moreover, FDA intends to test "healthy" symbols on a set of mock products whose product categories are likely to contain multiple products that currently meet FDA's regulatory definition of "healthy" – we are making no claims about the relative healthfulness of any product. Using these mock products in our research will provide us with sufficient information to understand how consumers might respond to a "healthy" symbol on food packaging, and that information is our goal with these studies. Testing the selected products will give us sufficient information to continue development of a proposed "healthy" symbol.

The comment did not provide an explanation for its recommendation to test "healthier" and "less healthy" products for each food product category. We are not testing "healthier" and "less healthy" versions of a given product in this research effort, as the goal of the research is to gauge participants' reactions to a symbol. Additionally, we are working on updating our definition of "healthy" and will describe our proposed updated definition in any related rulemaking. It would be inappropriate to assign relative "healthfulness" to comparator products. Products bearing the "healthy" symbol, which would be a graphic version of the nutrient content claim "healthy," would have to meet the criteria for using the claim.

(Comment 16) One comment noted a symbol with the term "FDA" may cause confusion if that symbol is used on any products regulated by the U.S. Department of Agriculture (USDA) and urged us to consider the potential for such confusion in our research. Another suggested that we engage with the Food Safety and Inspection Service (FSIS) during our proposed consumer research on the "healthy" symbol to develop a symbol that could apply to all products that meet the "healthy" claim criteria.

(Response 16) We cannot comment on whether or how USDA might allow an FDA "healthy" symbol on the products it regulates that meet FDA's definition of "healthy."

However, we intend to coordinate with our federal partners, including USDA, as appropriate, as we continue our work on a "healthy" symbol.

(Comment 17) A few comments asserted it was important to consider the symbols' placement on packaging and noted that food packaging size, type, and appearance vary, suggesting that FDA should study how consumers may respond to a "healthy" symbol on a wider variety of packaging formats than are currently proposed for the studies. One comment suggested testing the symbol on different locations on the package and with varying prominence. Another encouraged flexibility in specified requirements (e.g., placement, type size, color format, scannable images) surrounding the FOP symbol.

(Response 17) We anticipate that any "healthy" symbol we propose would be standardized in certain ways. However, the purpose of this research is to gauge consumer responses to the symbols we are testing, not to decide on a single symbol, its potential placement on packaging, or what aspects we would require, should a company choose to use the symbol.

(Comment 18) A few comments suggested we include questions or conduct additional research to assess the potential for consumer misunderstanding of the symbols. Some comments suggested that we investigate whether consumer perceptions of some symbols might imply messages other than "healthy" (such as "organic," "natural," "plant-based," and "minimally processed") or whether the symbols we are testing may appear similar to other existing or abandoned symbols (such as the USDA Organic Seal, Smart Choices, or any of USDA's bioengineered food symbols). One comment claimed that a lack of legibility of the text in the symbol could cause consumer confusion. Another comment recommended that FDA avoid leaf or nature imagery in the symbol because it could imply that the product is plant-based, "natural," or unprocessed. One comment encouraged us to examine how appealing the symbols are to consumers, and another comment described the proposed symbols as too simplistic.

(Response 18) We have selected study designs and draft symbols that we expect, when used together, will reveal how consumers will react when they see such symbols on a food label. We included questions in our studies on what the symbols lead participants to believe about the products bearing them. We also expect to hear from participants whether the symbols we are testing are perceived as too complex, too simplistic, or invoke concepts other than "healthy."

We agree that any symbol we propose should be legible and minimize imagery that our research indicates could widely lead consumers to think the symbol means something unintended. As such, we will add an open-ended question to the experimental study asking what the symbol brings to mind to help determine if any symbols should be removed from consideration or revised on this basis. Moreover, we agree that the FDA symbol design for "healthy" should not be easily confused with other existing symbols and should be viewed as professional and credible by consumers. We expect to get some data on these points through this round of testing and may undertake further research before we make any formal regulatory decision on a symbol.

(Comment 19) One comment suggested that FDA test other terms besides "healthy," such as "nourishing" or "nutrient-dense."

(Response 19) We are not testing the nutrient content claim "healthy;" rather, we are testing consumer responses to graphic representations of the claim. We similarly do not intend to test other terms.

(Comment 20) Several comments supported conducting research on the use of an accompanying URL with the "healthy" symbol; however, others stated the purpose for including a URL was unclear, and one comment expressed concern that a URL would not work as well in a brick-and-mortar retail setting. Another comment stated that future labeling could include the use of other technologies, such as a QR code or digital watermark, to provide consumers access to all the labeling information included on the package and suggested that we incorporate digital disclosure flexibility into our labeling regulations because technology continues to evolve. Other comments suggested that consumers may not have internet access in stores or may not know how to use QR codes, while another comment suggested that researchers could develop unique QR codes for each condition and track participant use.

(Response 20) Our research efforts on the "healthy" symbol are intended to collect sufficient data for the development and finalization of a "healthy" symbol. We are studying several dimensions of a proposed symbol, including the inclusion of a URL as part of the symbol. This research will help us better understand study participants' reactions to and understanding of those different elements.

Our preliminary research indicated that participants are interested in learning more about the symbols, and a URL can serve as a representation to participants that more information is available. The current study design proposes to test a URL alongside some of the symbols to gauge the ability of the URL to indicate that information about the symbol is available and to assess the degree to which a URL improves confidence and trust in the symbol. We are not studying participants' actual ability to access the URL in stores or elsewhere. We are also not considering inclusion of other technologies, such as a QR code or digital watermark, in this information collection because a URL will help us gauge whether participants want a way to access additional information about the symbol. Further, a QR code or digital watermark would not indicate government involvement in the way a URL ending ".gov" may, and we are interested in how participants will respond to a ".gov" URL.

While we agree that technology changes over time, we are only studying consumer responses to the symbols in this research. It would be premature to comment on any requirements surrounding any symbol we might propose. However, we could consider other digital elements, such as QR codes or digital watermarks, in future research depending on our future research goals.

(Comment 21) Some comments raised concerns that the use of FDA's name as part of the "healthy" symbol. The comments said that the use of FDA's name could create the appearance of an FDA endorsement of a given food.

(Response 21) We are testing draft symbols with "FDA." We note that we are studying several dimensions of a proposed symbol to help us better understand study participants' reactions to and understanding of those different elements, including any impression of an FDA endorsement.

(Comment 22) A few comments expressed uncertainty as to whether FDA research participants would come from a nationally representative sample and recommended paying particular attention to or using quota samples similar to the demographic breakdown of the U.S. population regarding sex, age, race/ethnicity, income, and education. Some comments also stated that FDA should consider oversampling from certain groups at highest risk for dietary-related disparities, asserting that it is important to ensure that any proposed healthy symbol works well among all populations. One comment noted this is especially important for lower-education groups who, the comment asserted, may be less likely to use or understand the package's nutrition label. Some comments also requested that FDA screen participants to ensure a sample large enough to collect responses from food-allergic individuals, caregivers to food-allergic individuals, and parents.

(Response 22) We designed our studies to test consumer responses to draft symbols in a randomized controlled setting, with participants drawn from a general population. Our research collection is not intended to produce population estimates. However, we intend to select the samples in each study to be reflective of the general U.S. population (e.g., sex, race/ethnicity). We believe our approach is reasonable because any "healthy" symbol we finalize will be available to the general U.S. population.

(Comment 23) One comment suggested that we test a Spanish language version of the symbol and consider whether including "FDA" as part of the symbol would resonate with consumers of products sold in other countries.

(Response 23) Our regulations, at 21 CFR 101.15(c), generally require that the labeling of all food offered for sale in the United States be in English, and outline requirements for manufacturers that also choose to label their products in additional languages. Because we generally require only English labeling, and manufacturers may choose whether to use or include foreign-language labeling, we are testing only an English-language version of the symbol in this set of studies.

As for products sold in other countries, the nutrient content claim "healthy," and any related symbol we finalize, are specifically for products marketed and sold in the United States. We decline to comment on marketing and sales in, or the food labeling requirements of, other countries.

(Comment 24) One comment argued that we should not generalize the results from this study to all FOP label systems.

(Response 24) We agree that findings from this research should not be generalized to all FOP label systems.

C. Comments regarding ways to enhance the quality, utility, and clarity of the information to be collected, and FDA response

Several comments suggested ways to enhance the quality, utility, and clarity of the information about "healthy" symbols to be collected.

(Comment 25) Some comments stated FDA should conduct thorough research regarding the development and finalization of a symbol for "healthy," and should collect comprehensive data so that FDA's final decision promotes health.

(Response 25) FDA agrees with the comments. Our research goal is to explore consumer responses to draft symbols that could represent the nutrient content claim "healthy." The goal of the symbol is to help consumers make more informed dietary choices.

(Comment 26) Several comments recommended we change certain aspects of the questions we include in the experimental study. Some comments suggested that we select specific outcome measures, such as purchase intent, sales data, ability of the symbols to attract consumer attention, long-term behavior change, consumer perceptions of the taste and cost of products bearing the "healthy" symbol, the healthfulness of the products consumers purchased, the number of "healthier" products purchased in a shopping setting, and any unintended consequences of the symbol.

One comment recommended adding covariates, such as health status, particularly for conditions that are related to nutrition, such as diabetes, weight status, and hypertension, to help us understand responses. Regarding the interpretation of measurements, one comment suggested we avoid "believability" or "trustworthiness" as indicators of which symbol can help people make more informed dietary choices, claiming that these are not strong predictors of behavior. The comment cited a study on cigarette pack warning messages that found that measures on the effects of the warning message resulted more in intended behavior change than did measures on attitude perceptions (Ref. 6).

Another comment recommended FDA provide an option for open-ended responses to gauge consumers' perceptions of "healthy."

(Response 26) The intended studies cover the key measurements and covariates that will help us understand consumer perceptions of the symbols. The comments did not provide, and we are not aware of, evidence that adding covariates or measurements would enhance the quality, utility, or clarity of the information we intend to collect. We will evaluate our draft symbols based on our analysis of all – not just a subset – of these measurements. We acknowledge that there are measurements we are not including in this research effort

(e.g., long-term behavior changes). These studies are designed to explore consumer responses to the draft symbols, and inclusion of variables such as long-term behavior changes would be premature.

We plan to use a variety of measures to help understand the potential impact of a voluntary FOP symbol for "healthy," and intend to use "believability" and "trustworthiness" as outcome measures because well-established scientific literature has shown that consumers' attitudes and perceptions affect their behavior (Refs. 7 to 9). Additionally, we note that the cigarette-pack study one comment cited qualified its findings as unsure if the same would be found in other message or product scenarios (Ref. 6). Because the published literature does not indicate that "effects perception measures" have been tested in the food label domain, we will add some questions to the experimental study to evaluate their use as outcome measures compared to "message effects measures."

We disagree with the suggestion to query consumers on their perception of "healthy." Our research is designed to test consumer responses to the draft symbols, not determine consumer perceptions of "healthy."

D. Comment regarding ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology, and FDA response

One comment discussed minimizing the information collection burden on respondents to our proposed "healthy" symbol research.

(Comment 27) One comment supported the proposed research and noted that the use of online surveys will help alleviate participant and administrative burden while ensuring that the research reaches sufficient participants.

(Response 27) We agree with the comment for the purposes of this research.

E. Nonresponsive comments to the PRA

Some comments addressed aspects of "healthy" symbols that are outside the scope of this information collection or addressed issues other than the "healthy" symbol research. These discussed, for example, the definition of "healthy," potential impacts of the "healthy" nutrient content claim generally, whether the symbols should be voluntary or mandatory, and whether we should develop an accompanying consumer education campaign. These are outside the scope of this information collection, and we will not address them here. Interested parties will have an opportunity to comment on any "healthy" symbol we propose and any proposed updated definition of the nutrient content claim "healthy" in response to their respective *Federal Register* notices.

9. Explanation of Any Payment or Gift to Participants

Experiment and Survey. Participants in the cognitive interviews will be recruited from an online consumer panel, and all cognitive interviews will be held online. Each participant will receive a cash incentive of $75 to participate in a one-hour interview.

Survey. The overall sampling frame for the surveys is the Ipsos Online Panel. The Panel is an actively managed research access panel that uses multi-source recruitment to maintain a base of respondents' representative of national demographic distributions. The Panel includes individuals who have volunteered to take part in market research.

Survey participants receive an incentive for participating in the Panel. They receive points for completion of surveys, and the points can be redeemed for cash or prizes.

Experiment. Experimental study participants will be drawn from a panel maintained by Prodege. Prodege incentivizes its Internet panel members with a digital currency for participation in surveys and other online activities. This digital currency can be used to purchase gift cards with well over a hundred options to choose from and/or can direct it to 501C3 charitable organizations. The appropriate incentive that panel members receive for participation is based on multiple factors including an approximate length of the survey and audience (i.e., business professionals vs. general consumers). Some examples of incentive partners include Amazon, Pizza Hut, Best Buy, Macy's, American Airlines, Hertz, Target, iTunes, etc. Charitable groups include groups like The American Red Cross and Wounded Warriors. There is no additional payment or gift associated with participation in the study proposed here.

Consumers are invited to join the Panel directly through Prodege's network of portal sites and complete a double opt-in registration process with multiple verification steps including CAPTCHA, IP Address verification, and mobile device reputation check. Currently, Prodege's Panel has over 100 million participants worldwide.

10. Assurance of Confidentiality Provided to Participants

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR will collect personally identifiable information (PII). The PII collected typically consists of name and contact information. PII is collected on behalf of the FDA by a contractor or vendor who conducts surveys. PII is collected in the context of studies on consumer self-reported responses to survey questions which include reacting to a variety of symbols that FDA is exploring for representing the nutrient content claim "healthy." Information collected by the vendor or contractor will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after

the study or interview has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. All individual information collected will be kept secure by the vendor or contractor. FDA and any vendor or contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors or vendors maintaining information will destroy it in accordance with applicable records retention and other requirements per contract terms after the aggregate information has been provided to FDA and the survey has been completed. In keeping with IRB/Human Subjects Research protocols, the clearance process ensures that study data is appropriately secured (e.g., housed on the Contractor's servers, password protected, separate storage areas for each study, access controlled).

FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to routinely retrieve records from the information collected.

All data will be collected with an assurance that the participants' answers will be kept secure to the extent provided by law, and the study instruments will contain a statement to that effect. Information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). As noted above, identifying information will not be included in the data files delivered by contractors to the agency.

The contractors will not share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the data files delivered to the agency. FDA will receive data for analysis in aggregate form. Although Prodege and Ispos retain contact information on participants for honoraria purposes, individually identifiable information is not shared with anyone, including FDA and its contractors; it is stored separately from the survey data file and is not linked in any way to participant responses.

The contractors maintain restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. The contractors will take the following security measures to ensure separation between participants' identity and their survey data. First, questionnaires and survey instruments have no personally identifying information (PII) on them. No participant name, address, email address, phone number or any other kind of PII appears on the instruments. The only way a survey is identified is with a digital identification number. Second, while the invitation method, whether email, mail or direct mail will inherently have PII information included, this will not be combined with survey responses, so the responses from the

survey are not linked to the PII. Third, screener data shall be considered part of the survey data. The contractors will provide the results of the screener questions for all panelists, regardless of whether they qualify for the study. However, the contractors will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, the contractors will retain study records for the duration of the study. Upon final delivery of data files to the contractors and completion of the project, the contractors will destroy all study records including data files upon request. The contractors will not be able to supply or access this information for any reason, even at the request of FDA or the contractors, once destroyed. Finally, data coming directly from the survey engine are stored in a proprietary database. While this data is not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to the contractors will be sent via encrypted files.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey and experimental study instruments do not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1. Estimated Annual Reporting Burden[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Study 1 (Survey) Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Study 2 (Experiment) Cognitive interview screener[2]	75	1	75	0.083 (5 minutes)	6

Study 1 (Survey) Cognitive interview	5	1	5	1 (60 minutes)	5
Study 2 (Experiment) Cognitive interview	9	1	9	1 (60 minutes)	9
Study 1 (Survey) Pretest	60	1	60	0.17 (10 minutes)	10
Study 2 (Experiment) Pretest	180	1	180	0.25 (15 minutes)	45
Study 1 (Survey)	2,000	1	2,000	0.17 (10 minutes)	340
Study 2 (Experiment)	5,000	1	5,000	0.25 (15 minutes)	1,250
Total					1,671

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

The annualized cost to all participants for the hour burden for the collection of information is $36,762. (1,671 x $22). The rate of $22 per hour is the 2021 median wage rate in the U.S., rounded to the nearest dollar. [1]

13. Estimates of Other Total Annual Costs to Participants and/or Recordkeepers/Capital Costs

There are no capital, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection is $300,000. This includes the value of the task orders to develop and conduct the collection of information and the value of a Full-Time-Employee to develop and monitor the data collections and then analyze the results.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed December 2021.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform the continued exploration of a symbol for voluntary use on the food label to depict the nutrient content claim "Healthy." The Agency anticipates disseminating the results of the research after the final analyses of the data are completed, reviewed, and cleared. Results of the research may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities is shown in Table 2.

Table 2. *Project Schedule*

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractors to proceed with data collection activities	Not applicable
Within 135 days after notification to contractors	Completion the experimental study and both surveys	Not applicable
Within 180 days after notification to contractors	Delivery by the contractors of experimental study and survey final data files	Not applicable
Within 6 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. In addition, journal manuscripts and oral and/or poster presentations will be planned for disseminating information to the public, including professionals, academics, and industry and consumer organizations. The dialogues will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.

References

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