We have received requests for a 90-day extension of the comment period for the draft guidance. We have concluded that it is reasonable to extend the comment period for 90 days, until September 25, 2023. (A 90-day extension would fall on September 24, 2023, which is a Sunday, so we have extended the comment period until the next business day, which is September 25, 2023.) We believe that the additional time allows adequate time for interested persons to submit comments.

Dated: June 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12790 Filed 6–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by July 17, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Quantitative Research on Front of Package Labeling on Packaged Foods.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Quantitative Research on Front of Package Labeling on Packaged Foods

OMB Control Number 0910–NEW

I. Background

The United States continues to face an epidemic of diet-related chronic diseases, many of which are experienced disproportionately by racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas (Ref. 1). To help address this problem, FDA has continued to prioritize its nutrition activities (Ref. 2) to help empower consumers with nutrition information to make healthier choices more easily and encourage industry innovation by providing flexibility to facilitate the production of healthier foods. FDA is focused on: (1) creating a healthier food supply for all; (2) establishing a healthy start to set the foundation for a long, healthy life; and (3) empowering consumers through informative labeling and tailored education (Ref. 2; see also Ref. 3).

FDA is exploring the development of a front of package system to help consumers interpret the nutrient information on food products. Front of package (FOP) labeling is intended to complement the Nutrition Facts label by giving consumers a simple aid to provide additional context for making healthy food selections. As part of our food-labeling efforts, we are exploring the establishment of a standardized, science-based FOP scheme that helps consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy dietary pattern.

The increased attention in recent years to FOP and the experiences of countries that have adopted FOP labeling suggest that FOP labeling may aid nutrition comprehension and the ability to make healthier choices, especially for those with lower nutrition literacy. FOP schemes adopted in countries throughout the world include both mandatory and voluntary labeling schemes and noninterpretative, interpretative, nutrient specific, and summary schemes.

In 2022, FDA conducted a review of the literature on FOP nutrition-related labels and conducted a set of focus groups to test FOP concepts and draft FOP schemes (see Docket No. FDA–2023–N–0155 for the literature review). These focus group results provided insights into the varying ways that consumers interpret FOP nutrition information. As part of our efforts to promote public health, we intend to conduct an experimental study, informed by results of the focus group testing, to further explore consumer responses to various FOP schemes. In the experimental study, we will test a smaller subset of FOP schemes from the focus group testing, with additional variations informed by, among other things, focus group results (see *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=253321* for information about FDA's front of package focus groups, including graphic FOP schemes tested). The study will be a controlled, randomized experiment that will use a 15-minute web-based questionnaire to collect information from 9,000 U.S. adult members of an online consumer panel maintained by a contractor. The sample will be balanced to reflect the U.S. Census on gender, education, age, and ethnicity/race. A measure of nutrition literacy will also be used to balance the sample to ensure a variety of literacy levels for each condition.

Conditions for the study will be: (1) a set of draft FOP schemes, including ''no-scheme'' controls; (2) three types of mock food products (*i.e.,* a breakfast cereal, a frozen meal, and a canned soup); and (3) a ''no-information'' condition where no explanation of the FOP scheme is provided. The experiment will have two main parts: (1) a within-scheme comparison and identification of healthfulness profile and (2) a single-product (and scheme) evaluation. In part 1, participants will see three levels of healthfulness (most healthful, middle, and least healthful) on a single scheme and be asked to identify the most and least healthful profile. Participants will be timed and will be provided with a link to a Nutrition Facts label in case they want more information to answer the question. Each participant in part 1 will evaluate three different sets of schemes. In part 2, each participant will be randomly assigned to a single condition (food product, scheme type, or level of healthfulness). In this section, participants will be asked to use the label image to respond to various measures of the label's effectiveness. Product perceptions (*e.g.,* healthfulness and contribution to a healthy diet) and label perceptions (*e.g.,* believability and trustworthiness) will constitute the

measures of response in the experiment. 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 our continuing effort to help enable consumers to make informed dietary choices and construct healthful diets. We intend to use the results to inform our continued exploration of an FOP labeling scheme. We will not use the results to develop population estimates.

Description of Respondents: Respondents to this collection of information include members of the general public.

In the **Federal Register** of January 26, 2023 (88 FR 5005), FDA published a 60-day notice requesting public comment on the proposed collection of information (60-day notice). We received 26 comments, 2 of which were duplicates. Of the other 24, 20 were related to the PRA. The remaining comments were nonresponsive to the four PRA topics, so we will not address them in this document. We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

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 an FOP scheme that would provide information to consumers to help them make more informed food choices.

(Comment 1) Many comments supported FDA's proposed collection of information through an experimental study. Many supported our consumer research, including the study design, goals, and research on schemes. Several other comments suggested that the study has limitations because it only assesses purchase intention and how consumers say they will behave, and not actual purchase or consumption behaviors.

(Response 1) As is common with research in the scientific literature, our study design mimics, as much as possible, how consumers will respond to a FOP nutrition label scheme (Refs. 4 and 5). Assessing actual purchase or consumption behavior is not possible because the schemes to be tested are not currently available in the marketplace. Additionally, the overall focus of this research is to assess consumer understanding of FOP schemes that may help consumers interpret certain nutrient information on food products; it is not meant to assess actual purchase or consumption behaviors.

B. Comments Regarding the Accuracy of Our Burden Estimates, Including the Validity of the Methodology and Assumptions Used, and FDA Response

Some 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 2) Multiple comments encouraged FDA to increase transparency in our FOP research, with some expressing concern that the public has not had sufficient opportunity for input on the burdens of the information collection or the utility of the research due to a lack of information. Many comments urged us to provide more information on factors such as the specific objectives of the research; research and study design; methodologies; survey questions; visual product label mockups; the FOP schemes to be tested; FDA's basis for choosing the FOP schemes we have decided to test and excluding those we have excluded; nutritional criteria being tested, including the criteria for any color coding or ''High in'' schemes; the outcomes from our focus groups and any other past surveys and consumer research; an analysis of foreign FOP schemes; and the variables and conditions to be tested. One comment asked how we developed the schemes used in the focus groups, particularly those that contained the terms ''low,'' ''medium,'' and ''high,'' given that FDA has not defined or applied these terms in the context used in the focus groups.

A couple of comments suggested that FDA should collaborate with stakeholders when conducting studies or developing an FOP scheme in the future.

(Response 2) Detailed information and all study materials are available at *https://www.reginfo.gov.* The literature review and FOP schemes are also available in the docket (Docket No. FDA–2023–N–0155). The schemes to be tested include variations on schemes that are currently available in the marketplace and others that attempt to interpret certain nutrition information. We developed schemes based on insights from our focus groups, analysis of the literature on FOP labeling, and review of schemes from other countries. We recognize that these schemes are a subset of the many possible schemes that could be tested, and we selected them for the reasons described above.

Regarding nutritional criteria and the ''low,'' ''medium,'' and ''high'' designations, for the purposes of the focus groups and experimental study, we have defined the nutritional criteria and the ''low,'' ''medium,'' and ''high'' designations to be based on the percent Daily Value (see, *e.g., https://www.fda.gov/food/new-nutrition-facts-label/lows-and-highs-percent-daily-value-new-nutrition-facts-label*). The study refers to these criteria.

FDA has collaborated with stakeholders on the exploration of the FOP schemes through our focus-group testing, 60-day notice, and this notice, and any regulatory action we take after our testing will be published in the **Federal Register** for public comment.

(Comment 3) One comment said FDA did not provide enough information in our 60-day notice on our testing, including the number of label conditions, the number of food choices respondents will have, whether there will be a separate control group, and a primary study outcome, to allow the public to evaluate the suitability of our proposed sample size.

(Response 3) The 60-day notice included information about the study to allow members of the public to provide comment. Detailed information and all study materials are available at *https://www.reginfo.gov.* The literature review and FOP schemes are also available in the docket (Docket No. FDA–2023–N–0155). There will be 10 total label conditions, 3 food types, and a control group that will see a label with no scheme. Primary study outcomes include the ability to correctly interpret the nutritional profile of the product, the speed at which participants make their decisions, and their search for more information to answer the question (*i.e.,* whether they want to view the Nutrition Facts label). The proposed sample size is 9,000 participants.

C. Comments Regarding Ways To Enhance the Quality, Utility, and Clarity of the Information To Be Collected, and FDA Response

Many comments suggested ways to enhance the quality, utility, and clarity of the information about the FOP schemes to be collected.

(Comment 4) One comment said we should avoid color coding or ''low,'' ''medium,'' or ''high'' markers in our scheme because it is unwise to base a food's healthfulness on one factor alone. Another comment said that color-coding nutrients to limit and nutrients to encourage in the same scheme would

confuse consumers and that we should include an option that does not color code nutrients to encourage. A few comments said that we should present some schemes in black and white and others with color to identify if color should be used. Several comments said that we should only test schemes that industry could implement without excess cost or burden.

(Response 4) Color-coding and interpretational aids such as ''high,'' ''medium,'' and ''low'' are being tested because prior research has found such interpretive components helpful to consumers when evaluating the nutritional profile of products (Refs. 6 and 7). We disagree that testing these interpretational aids bases a food's healthfulness on one factor alone; rather, the schemes we are testing are intended to complement the Nutrition Facts label by giving consumers a simple aid to provide additional context for making healthy food selections.

The study will test both color and black-and-white schemes (see Docket No. FDA–2023–N–0155). We are not currently planning to test schemes that include both nutrients to limit and nutrients to encourage, so there will be no options in the study that cover nutrients to encourage.

Regarding the cost of implementation, this quantitative study focuses on gathering information. Should we move forward with a regulatory action, we will consider potential economic impacts of any proposed scheme.

(Comment 5) One comment recommended that FDA conduct indepth interviews with diverse stakeholders because such interviews facilitate better understanding and add nuance to findings.

(Response 5) We have incorporated a variety of qualitative research methods, including the use of interviews, as part of our research. The study will employ cognitive interviews before we conduct the proposed experiment to test whether and how participants understand the study questions and whether the design will reach our research goals. The study instrument will include an open-ended question, providing participants an opportunity to express top-of-mind reactions to the study and schemes. FDA also conducted focus groups on FOP nutrition labels in 2022, which have informed the proposed experimental study. We note that the quantitative nature of experimental studies allows for statistical generalizability of effects while qualitative designs do not.

(Comment 6) Some comments advocated testing consumption in the home or testing in real-world or simulated shopping environments. One comment advocated that the FOP schemes appear alongside other commonly found symbols on food labels.

(Response 6) 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.

Participants will view the schemes on mock food labels that closely match those found in grocery stores. The study will not assess the schemes alongside other commonly found symbols on the food label. Our studies are designed to test general consumer responses to the schemes presented. Testing additional variables, such as the effect of other packaging elements on the schemes, is outside the scope of this research. We are not testing consumption in the home because, again, our studies are designed to test general consumer responses to the schemes presented. We are not studying consumption behavior.

(Comment 7) A couple of comments said that mockups of product labels should accurately represent products in the marketplace, and that the mockups we used in the focus-group testing included unrealistic elements, such as fewer competing claims, small type size for voluntary claims, and fonts not commonly used on product labels. Several comments asserted that we should ensure label mockups are realistic, and a few comments maintained that the mockups should not introduce bias.

(Response 7) FDA disagrees with the comment that its mock food packages contain unrealistic elements, and the comment provides no support for the claim that our chosen type size and fonts are not commonly used on product labels. While we recognize that our mockups contain fewer competing claims than might be on some real packages, the mock packages represent products that might be found in the actual marketplace and reflect a real-world food product scenario without the introduction of bias that may come with including competing symbols or claims.

(Comment 8) One comment urged us to develop research objectives that pair with our policy objectives. The comment recommended that we add the following goal of FOP labels: ''To help people quickly and easily identify foods that, when consumed, may lead people to exceed daily nutritional recommendations for nutrients of concern (sodium, added sugar, and saturated fat).'' The comment also recommended that FDA establish more specific research objectives relating to encouraging healthier food selections, enabling consumers to identify foods that are part of a healthy eating pattern, and identifying foods associated with nutrients of concern. A few comments said we need to clearly define the quantitative consumer research's primary outcome so that we can develop questions and research designs that will address the intended goal. One comment said that, before conducting the quantitative study, FDA should identify the metrics for consumer understanding to guide the study design and interpretation of results.

(Response 8) The goal of our research is to assess which FOP scheme best enables consumers to identify foods that can help them build a healthy eating pattern. We decline to add any other research objectives because we believe that our stated research goal most closely corresponds to our policy objectives.

Regarding the research's primary outcome, we noted earlier that our primary study outcomes include the ability to correctly interpret the nutritional profile of the product, the speed at which participants make their decisions, and their search for more information to answer the question (*i.e.,* want to view the Nutrition Facts label). We believe we have developed questions and research designs that will address our intended goal.

We agree that we should identify the metrics for consumer understanding to guide the study design and interpretation of results. An element of the study design process includes identifying appropriate metrics for measuring consumer understanding. These metrics will help FDA interpret the study results.

(Comment 9) Many comments urged FDA to research how FOP schemes would impact consumer behavior, including purchase or consumption decisions. One comment encouraged us to study consumers' selection of calories and nutrients, foods that meet our proposed definition of ''healthy,'' and foods high in added sugars, sodium, or saturated fat. A few comments said we should measure whether, and why, the schemes would affect intended purchase or consumption frequency. A couple of comments recommended

testing whether the presence of an FOP scheme makes consumers more likely to read and understand the Nutrition Facts label. Some comments suggested specific methods for studying and evaluating consumer behavior.

A few comments asserted that research on consumer behavior and how consumers use and understand FOP labeling is necessary to avoid consumer confusion, misleading consumers, and unintended consequences. Another comment recommended that FDA's research assess whether consumers interpret the label to have the same meaning that FDA intends.

(Response 9) We acknowledge that there are measurements we are not including in this research effort (*e.g.,* behavior changes). These studies are designed to explore consumer responses to the schemes, and inclusion of variables such as behavior changes would be outside of the scope of our research.

The study will measure whether participants can understand the scheme when trying to identify certain nutrient profiles. The study will also include an option for participants to view the Nutrition Facts label if they so choose, but the study will not evaluate reading and understanding of the Nutrition Facts label because this is not the goal of the study.

(Comment 10) One comment encouraged us to assess consumer understanding of product healthfulness using objective measures (*i.e.,* questions with factual answers). Some comments urged FDA to include open-ended questions in our survey.

(Response 10) One of the goals of the research is to assess consumers' ability to use the schemes to determine product healthfulness. In one part of the study, participants will see three versions of a scheme and will be asked to identify the scheme with the most healthful nutritional profile and the scheme with the least healthful nutritional profile. The profiles are based on FDA's characterization of levels of the percent Daily Value as either ''high'' or ''low'' (see *https://www.fda.gov/food/new-nutrition-facts-label/lows-and-highs-percent-daily-value-new-nutrition-facts-label*). The questionnaire will have at least one open-ended question seeking general feedback on the study and schemes.

(Comment 11) One comment encouraged us to assess the trustworthiness of the schemes. Conversely, another comment opposed factoring in participants' ratings of believability and trustworthiness because, according to the comment, those factors are not strong predictors of real-world responses. Another comment said we should evaluate the reliability of respondents' answers versus real-life consumer behavior by considering the statistical significance of the study.

(Response 11) The study will include measures of trustworthiness and believability of the schemes, and these will be considered along with the other outcome measures. With respect to factoring in participants' ratings of believability and trustworthiness, many factors contribute to how people respond in the real world; thus, it is important for the study to include a variety of outcome measures while also limiting the scope to just the pertinent factors. We plan to conduct tests of statistical significance to evaluate the probability that the study findings are true patterned responses.

(Comment 12) One comment argued that our research design should consider the limitations of FOP schemes. Another comment encouraged FDA to expand our research plans to include more settings and to consider approaches that mitigate hypothetical bias.

(Response 12) The research will take into account the many factors that may limit consumers' ability and motivation to use FOP nutrition labels, such as nutrition literacy, Nutrition Facts label usage, time limitations, and health considerations. FDA disagrees with the comment encouraging us to expand the research to include more settings. FDA is designing the study so that the questions or tasks mirror how consumers typically approach food label reading. Additionally, as we noted above, results in naturalistic 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. However, cognitive interviews and pretests will help to improve the ''real-world'' feel of the questionnaire.

FDA's study is designed to mitigate hypothetical bias because it focuses on perceptions and understanding of the FOP schemes rather than on trying to assess behaviors associated with them.

(Comment 13) Multiple comments recommended FDA use industry materials or schemes in our testing, such as Facts Up Front and Consumer Brands' FOP nutrition labeling principles. Several comments urged us to test variations of the Facts Up Front scheme, with some reasoning that Facts Up Front has widespread adoption and that consumers are already familiar with the program and understand how to use it.

(Response 13) FDA is planning to test a scheme that includes attributes of the U.S. industry-established FOP schemes.

(Comment 14) Some comments said we should consider flexibility and exemptions to address space limitations regarding font size, style, and placement in our quantitative research.

(Response 14) The research will test placement on the food label but will not test font size and style. Contemplating flexibility and exemptions relating to issues such as font size and style on packages with space limitations is not the purpose of this study, which is to gauge consumer responses to the schemes we are testing.

(Comment 15) One comment said FDA should test how digital disclosure could replace an FOP scheme on the package.

(Response 15) The goal of our current research focuses on exploring FOP schemes that help consumers quickly and easily identify foods that can help them build a healthy eating pattern. We are not currently testing digital disclosures because that approach does not align with our research goals relating to the speed and ease with which consumers can assess foods.

(Comment 16) A few comments cautioned against using schemes that overlook, or mislead consumers about, a food's whole contribution to the diet or subjectively characterize a food (for instance, as ''High in,'' ''medium,'' or ''low in'') based on just three nutrients.

(Response 16) FDA is interested in learning how the different schemes to be tested help consumers put a food, as a whole, into the context of their daily (or longer-term) diets. The schemes included in the experimental study do not subjectively characterize a food based on three nutrients. The ''high,'' ''medium,'' and ''low'' designations included in the study are based on established criteria for interpreting the percent Daily Value of a nutrient (see, *e.g., https://www.fda.gov/food/new-nutrition-facts-label/lows-and-highs-percent-daily-value-new-nutrition-facts-label*) and the study refers to these criteria.

(Comment 17) One comment said that our research should maximize opportunities to include nutritious foods that are widely available and within the purchase reach of most consumers.

(Response 17) The mock food product categories to be included in the experiment are those that are highly consumed by many consumers of all economic levels (breakfast cereal, frozen meals, and canned soup). There are a variety of foods in these categories,

which in turn can vary widely in terms of healthfulness.

(Comment 18) One comment recommended that FDA test a label that states: ''WARNING: HIGH IN [sodium/added sugars/saturated fat]'' accompanied by a warning icon.

(Response 18) Our research goal focuses on exploring ways that FOP labels can complement the Nutrition Facts label on packaged foods by giving consumers additional context to quickly and easily identify foods that can help them build a healthy dietary pattern. Our research will test schemes that include a ''high'' designation or a ''High in'' statement as part of that goal. However, we will not test the word ''warning'' or a warning icon because doing so would not align with our research goals of learning how to provide consumers with additional factual context for food choices.

(Comment 19) One comment urged FDA to include low- and no-calorie sweeteners in the tested schemes because, according to the comment, the public wants to know if products contain such sweeteners.

(Response 19) Information relating to low- and no-calorie sweeteners is available to consumers in the ingredient list of a product. The focus of our study is to explore how to help consumers quickly and easily identify foods that can help them build a healthy eating pattern, with a focus on the nutrients that the Dietary Guidelines for Americans (Dietary Guidelines) have identified as nutrients to limit (Ref. 8).

(Comment 20) One comment said we could improve our schemes by limiting numerical information, emphasizing interpretive components (*e.g.,* a prominently placed ''High in'' designation), and adding attention-grabbing features. The comment also recommended against testing labels that highlight nutrients to encourage, because, according to the comment, companies already promote the healthy aspects of their products, and labels that combine both nutrients to limit and nutrients to encourage would create a challenge for consumer education.

However, other comments supported testing schemes with nutrients to encourage, arguing that the schemes must accurately reflect the full nutrient profile of a food; that the public should have tools to construct a healthy diet; and that, for instance, a product with some added sugar may be viewed as negative by the consumer if ''High in'' or ''red'' is marked on the FOP even if the product provides positive nutrition overall. A couple of comments claimed that many of the proposed schemes tested in the original focus groups reduced a food to its negative nutrients rather than recognizing its overall contribution to the diet and its positive nutrient and food group content.

Other comments advocated testing at least one scheme with a ''positive'' approach that would, for instance, award food stars depending on the food's nutrient content. A couple of comments said that we should also do consumer research on summary-based systems.

A couple of comments suggested that tested FOP schemes should align with the Dietary Guidelines to focus on overall dietary patterns rather than on individual nutrients.

(Response 20) The study will test a variety of schemes reflecting those currently found in the marketplace; some of them will contain limited numerical information and some will contain interpretive components. The study will assess consumers' ability to use the schemes to make decisions to support a healthful overall dietary pattern. As we noted earlier, the schemes we are testing are intended to complement the Nutrition Facts label by giving consumers a simple aid to provide additional context for making healthy food selections.

With respect to comments that urged FDA to test a ''positive'' approach or a summary-based system, we are testing different schemes based on our literature review and the feedback we collected through our focus group research, which indicate that simpler schemes are easier for consumers to understand and that consumers often already have access to information about nutrients to encourage on the front of food packages. As such, our current study plans do not include testing nutrients to encourage.

(Comment 21) One comment said it is important to understand whether consumers viewing an FOP scheme view the foods as ones that should be avoided, particularly for products that are healthful food choices recommended by the Dietary Guidelines or MyPlate.

(Response 21) The research will evaluate whether the FOP scheme assists consumers in identifying the healthfulness of a product or whether the scheme encourages them to avoid the product.

(Comment 22) One comment recommended against testing Guideline Daily Amount (GDA) labels with numeric information (*e.g.,* amount per serving or percent Daily Value) without an additional interpretive component. Conversely, a couple of comments requested that we also include GDA schemes without interpretive elements to help us understand the benefits and limitations of the schemes, with one comment suggesting that fact-based FOP schemes used by industry could be our control.

(Response 22) FDA is testing the effects of different kinds of schemes, including GDA-type schemes. Some of the schemes being tested have interpretational aids and some do not. Statistical analysis will allow FDA to use each of the tested schemes as a control for other schemes.

(Comment 23) One comment said that FDA should consider testing the effects of different FOP label designs both with and without additional information to aid in label interpretation.

(Response 23) FDA is testing the effects of different kinds of schemes, some that have interpretational aids and some that do not.

(Comment 24) One comment encouraged us to use survey measures with strong psychometric properties. For example, the comment said FDA should consider using the UNC Perceived Message Effectiveness Scale to assess effects perceptions.

(Response 24) FDA acknowledges the value of using measures that are reliable, have been validated, and that have strong psychometric properties. However, we do not believe that the UNC Perceived Message Effectiveness Scale is appropriate for this study because this study deals with the provision of nutritional information via food labeling.

(Comment 25) One comment recommended that we pre-register a protocol for the proposed experiment, including the primary outcome and all secondary outcomes, any hypotheses or predictions, the analytic plan, and the power calculations used to arrive at the target sample size.

(Response 25) FDA declines to preregister the research protocol, as described in the comment. The comment did not explain what additional details might be available via preregistration that would not be available in our **Federal Register** notices, in the docket (Docket No. FDA–2023–N–0155), and on *https://www.reginfo.gov.*

(Comment 26) A few comments said the foods tested should reflect more product categories, varieties, package sizes, and nutrient profiles that would be subject to an FDA FOP scheme. For example, some of these comments recommended that we test single-ingredient products, individual foods, and foods that are known to be higher in sugar, sodium, or saturated fat. Some comments said that without doing so, the research setting would be

unrealistic, and we may not be able to apply the study findings to all types of packaged foods, including beverages, available to consumers. One comment said that we should compare consumer reactions to FOP schemes across multiple food categories so that we can assess whether reactions to standardized FOP schemes might shift perception, purchasing, or consumption of certain products.

(Response 26) FDA declines to add more product types to the studies. We are proposing to test schemes on a set of mock products that belong to large food categories, with many product types within each category. The mock food product categories to be included in the experiment (breakfast cereal, frozen meals, and canned soup) are those that are highly consumed by many consumers of all economic levels. There are a variety of foods in these categories, which can vary widely in terms of healthfulness and the nutrients included in the schemes.

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 schemes. We also note that adding any products would increase the scope and cost of the studies while providing limited new information, and the comments provided no evidence that additional test products from other food categories, varieties, package sizes, and nutrient profiles would impact our study outcome.

(Comment 27) One comment encouraged us to search for and consider the design of previously conducted research on FOP schemes when designing our own consumer research.

(Response 27) FDA has conducted a thorough review of the scientific literature on FOP schemes and continues to monitor the emerging science.

(Comment 28) One comment recommended we test additional variables, including health status, whether respondents have nutrition-related conditions, caregiver status, English language literacy, and method of administration of the test, to assess how consumers understand and use FOP schemes. The comment also said that respondents should be primary shoppers and should span socioeconomic status. A couple of comments said we should include demographic data, such as racial and ethnic minority groups, those with lower socioeconomic status, those living in rural areas, and parents of minors, to improve understanding of behavior changes across demographic groups.

(Response 28) The study is designed to assess how consumers understand and use FOP schemes. Most of the variables mentioned are included in the study, including a measure of whether the participant is the primary grocery shopper in the household. FDA agrees that a measure of caregiver status could be useful. Therefore, we have added this variable to the study instrument.

(Comment 29) A few comments said our research must include diverse populations, including race, ethnicity, education status, nutrition literacy, and income level. The comment continued that our research should address the needs of the most vulnerable populations. A few comments said we could consider over-indexing or oversampling on key consumer constituencies, such as the populations the FOP schemes are meant to target and caregivers. A couple of comments expressed concern that those in underserved communities and those most at risk for diet-related disease may not have computers and may have unreliable or no access to the internet, making participation in the study difficult.

(Response 29) Our study will ensure that members of underserved communities and those most at risk for diet-related disease are adequately represented. Participants recruited for the study will include diverse populations, considering race, ethnicity, education status, nutrition literacy, rural residency, and other sociodemographic factors. The study will also oversample consumers with lower nutrition literacy levels to ensure that we can evaluate the findings against levels of nutrition literacy. The Pew Research Center reports that 93 percent of American adults use the internet (Ref. 9). The Institute of Museum and Library Services reports that approximately 312 million Americans (out of the total U.S. population of approximately 330 million, according to the 2020 U.S. Census) live in a public library service area (Ref. 10). Virtually all public libraries provide free internet access (Ref. 11). There is no requirement that participants have a computer, laptop, or tablet at home to participate in this study. In the past, participants in FDA-funded studies who did not have a computer at home have completed studies using outside resources; for example, a computer at the public library.

(Comment 30) Several comments said that we may need a larger sample size than 3,000 given the information provided and that the results of the quantitative study will impact the entire U.S. population.

(Response 30) FDA agrees with the comment, and we plan to increase the sample size to 9,000.

(Comment 31) One comment said we may need to include additional schemes in the testing to understand category-specific, pack size-specific considerations, such as the ''calories-only'' scheme sometimes used on foods in small packages. Another comment urged us to include some very small package mockups to ensure fit and readability of the FOP scheme. Similarly, another comment urged FDA to test a beverage option with a small or very small label to determine what nutritional information to include and whether a beverage container with a small label can bear an FOP scheme of readable size. Another comment stated that FDA's research should include various beverages among the products tested to ensure that FDA identifies differences in consumers' views between FOP labels on food versus beverages.

(Response 31) We are testing different schemes based on our literature review and the feedback we collected through our focus group research. The comments provided no evidence that including additional schemes in our testing would help us understand category-specific, package size-specific considerations. As such, FDA declines to add additional schemes to our testing.

FDA disagrees with the recommendation to add more product sizes or types, including beverages, to the study. 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 schemes to inform any future action we may take on the schemes. 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, including beverages, would impact our study outcome.

(Comment 32) One comment stated that calories should be included on most of the tested schemes. The comment asserted that energy is the most important component in diet planning and said that FDA must explain why we were not including calories. Another comment recommended that FDA include a calories-only icon in our research, while another comment wondered if the public would consume more overall

calories if FOP does not contain information on calories.

(Response 32) We decline to add calories to the schemes we are testing or test a calories-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 (see 81 FR 33741 at 33939, May 27, 2016). At this point, for the purposes of the 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. Regarding whether the public would consume more calories if FOP does not contain information on calories, this comment falls outside of the scope of our current research, which explores which schemes will provide consumers with additional information rather than shape consumer behavior.

(Comment 33) A couple of comments said FDA must consider how a standardized FOP scheme would interact with the voluntary ''healthy'' symbol FDA is studying. One of these comments encouraged us to evaluate whether having multiple FOP information systems could confuse consumers.

(Response 33) The purpose of this study is to evaluate how consumers understand a FOP labeling scheme. We are not considering the intersection of hypothetical label claims at this time, as we seek to conduct our study in a manner that minimizes bias. It is also outside the scope of our current quantitative research to test the effect of multiple FOP labeling systems. Rather, we are assessing how consumers understand the schemes that we are testing.

(Comment 34) A few comments encouraged us to update our literature review because, for example, schemes presented to respondents should reflect the latest science.

(Response 34) FDA agrees with the comment and has updated the literature review and continues to monitor the emerging scientific literature.

(Comment 35) One comment said we should review the results of studies on the long-term impacts and utility of FOP schemes, and not rely only on very recent studies.

(Response 35) FDA has been monitoring the scientific literature on FOP since 2006 and continues to monitor the literature, including any studies on long-term impacts and utility of FOP schemes.

(Comment 36) A couple of comments said we need to identify key metrics for success on label effectiveness, including how product perception, label perceptions, and nutritional qualities questions will be presented to the respondents, before conducting the study.

(Response 36) FDA plans to use product, label, and nutrition perception measures and will test these in cognitive interviews prior to conducting the pretests and the experiment.

(Comment 37) One comment recommended that we include readable samples of category users for each of the categories being presented (*e.g.,* cereal, frozen meals) and evaluate results among each relevant category user base.

(Response 37) FDA will include questions to assess whether participants use the product and will take this into account when evaluating the results.

D. Comments 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

No comments discussed minimizing the information collection burden on respondents to our proposed FOP scheme research.

E. Nonresponsive Comments to the PRA

Some comments addressed aspects of FOP schemes that are outside the scope of this information collection or addressed issues other than the FOP scheme research. These discussed, for example, whether the schemes should be voluntary or mandatory, specific ways to update the literature review, food allergies, requirements of any proposed FOP scheme, and constitutional and other legal issues with FOP requirements. 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 FOP scheme we propose in response to its **Federal Register** notice.

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
Pretest 1 Screener	800	1	800	0.05 (3 minutes)	40
Pretest 1	200	1	200	0.25 (15 minutes)	50
Pretest 2 Screener	800	1	800	0.05 (3 minutes)	40
Pretest 2	200	1	200	0.25 (15 minutes)	50
Experiment Screener	40,000	1	40,000	0.05 (3 minutes)	2,000
Experiment	9,000	1	9,000	0.25 (15 minutes)	2,250
Total					4,430

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

The number of participants in the study was increased from the 3,000 respondents estimated in the 60-day **Federal Register** notice to 41,600 with this publication. Therefore, the total burden has been increased from 3,205 responses and 801 hours to 51,000 responses and 4,430 hours because of the increase in the sample size for the pretests and the full experiment and screener. The reason for the increase in burden hours is because of a decision to

target consumers with higher and lower nutrition literacy levels, rural residence, and to ensure that the sample mirrors the demographic distribution of the U.S. population.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. Centers for Disease Control and Prevention. Overweight & Obesity, Available at: *https://www.cdc.gov/obesity/index.html*. Accessed on April 20, 2023.
* 2. FDA, FDA's Nutrition Initiatives. Available at: *https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives*. Accessed on April 20, 2023.
* 3. The White House, ''Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health.'' Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf*. Accessed on April 20, 2023.
4. Talati, Z., M. Egnell, S. Hercberg, et al. ''Food Choice Under Five Front-of-Package Nutrition Label Conditions: An Experimental Study Across 12 Countries,'' *American Journal of Public Health,* 109(12), 1770–1775, 2019.
5. Vargas-Meza, J., A. Jáuregui, A. Contreras-Manzano, et al. ''Acceptability and Understanding of Front-of-Pack Nutritional Labels: An Experimental Study in Mexican Consumers,'' *BMC Public Health,* 19, 1751, 2019.
6. Pettigrew, S., L.M. Dana, Z. Talati, et al. ''The Role of Colour and Summary Indicators in Influencing Front-of-Pack Food Label Effectiveness Across Seven Countries,'' *Public Health Nutrition,* 24(11), 3566–3570, 2021.
7. Song, J., M.K. Brown, M. Tan, et al. ''Impact of Color-Coded and Warning Nutrition Labelling Schemes: A Systematic Review and Network Meta-Analysis,'' *PLoS Med,* 18(10), e1003765, 2021.
8. U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020–2025*. 9th Edition. December 2020. Available at *https://www.dietaryguidelines.gov/resources/2020-2025-dietary-guidelines-online-materials*. Accessed on May 9, 2023.
9. Pew Research Center. Internet/Broadband Fact Sheet. April 7, 2021. Available at: *https://www.pewresearch.org/internet/fact-sheet/internet-broadband/*. Accessed on April 19, 2023.
* 10. Institute of Museum and Library Services. ''Public Libraries in the United States: Fiscal Year 2017,'' vol. 1, p. 2. June 2020. Available at *https://www.imls.gov/publications/public-libraries-united-states-survey-fiscal-year-2017-volume-1*. Accessed on April 27, 2023.
* 11. Samantha, B., M. Crandall, K. Fisher, et al. ''Opportunity for All: How the American Public Benefits From internet Access at U.S. Libraries,'' Institute of Museum and Library Services, March 2010, p. 32. Available at *https://www.imls.gov/sites/default/files/publications/documents/opportunityforall_0.pdf*. Accessed on April 27, 2023.

Dated: June 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12820 Filed 6–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Discovery and Functional Evaluation of Human Pain-associated Genes and Cells (U19) and Data Coordination and Integration Center (U24) Review Meeting.

Date: July 11–12, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Eric S. Tucker, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Rm. 3208, MSC 9529, Rockville, MD 20852, 301–827–0799, *eric.tucker@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; ALS Expanded Access Program.

Date: July 17, 2023.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: W. Ernest Lyons, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Rm. 3208, MSC 9529, Rockville, MD 20852, 301–496–4056, *lyonse@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: June 9, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–12792 Filed 6–14–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: July 14, 2023.

Time: 11:30 a.m. to 12:30 p.m.