

nominations are finalized in the OPPS/ASC final rule.

The information collected in this request will be used by CMS annually to determine what covered surgical procedures should be added to the ASC CPL. Specifically, the policy analysts and medical officers in the Division of Outpatient Care will individually review each procedure nomination, as well as any supporting evidence (clinical studies, literature, data or letters of support) submitted. The agency will use this information to propose a list of covered surgical procedures for the OPPS/ASC Proposed Rule starting with the CY 2025 Proposed Rule. *Form Number:* CMS-10809 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 15; *Total Annual Responses:* 100; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Nate Vercauteren at Nathan.Vercauteren@cms.hhs.gov.)

Dated: June 9, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-12773 Filed 6-14-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-1027]

Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance entitled “Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry,” that appeared in the **Federal Register** of March 27, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance published March 27, 2023 (88 FR 18149). Submit either electronic or written comments

on the draft guidance by September 25, 2023, to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-D-1027 for “Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450; or Philip Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 2023 (88 FR 18149), we published a notice of availability for a draft guidance entitled “Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry.” This action opened a docket with a 90-day comment period.

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.

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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