

respond rapidly to this devastating pandemic. This supplemental award will allow NORC to enhance the capacity of LTC Ombudsman programs to address abuse, neglect and exploitation as programs begin to re-enter long-term care facilities. This supplemental is consistent with the Coronavirus Response and Relief Supplemental Appropriations Act of 2021: Grants to Enhance Capacity of Long-Term Care Ombudsman Programs to Respond to Complaints of Abuse and Neglect of Residents in Long-Term Care Facilities during the COVID-19 Public Health Emergency.

*Program Name:* National Ombudsman Resource Center.

*Recipient:* The National Consumer Voice for Quality Long-Term Care.

*Period of Performance:* The supplement award will be issued for the time period of April 1, 2021-September 30, 2022.

*Total Award Amount:* \$25,000, FY 2021.

*Award Type:* Cooperative Agreement Supplement.

*Statutory Authority:* This program is authorized under Section 202 of the Older Americans Act.

*Basis for Award:* The objective of the National Ombudsman Resource Center is to support credible and effective Long-Term Care Ombudsman programs through the provision of technical assistance and training to state Ombudsman programs and to state agencies on aging. Each year the NORC helps thousands of state and local Ombudsmen through its website, training and webinars and specialized technical assistance. It is the only resource center specialized to provide technical assistance to state Ombudsman programs. In addition, early in the pandemic NORC pivoted to provide relevant tools and training to help Ombudsman programs respond to the pandemic including the toolkit COVID-19 Recover and Re-entry and Trauma-Informed webinars and dialogue to assist Ombudsman programs.

*For More Information Contact:* For further information or comments regarding this program supplement, contact Louise Ryan, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging (206) 615-2299; email [Louise.Ryan@acl.hhs.gov](mailto:Louise.Ryan@acl.hhs.gov).

Date: April 30, 2021.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0913]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

**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.

**DATES:** Submit written comments (including recommendations) on the collection of information by June 7, 2021.

**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 OMB control number for this information collection is 0910-0705. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRStaff@fda.hhs.gov](mailto:PRStaff@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.

#### 513(g) Request for Information

*OMB Control Number 0910-0705—Extension*

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency’s views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the

receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled “FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff”<sup>1</sup> establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA’s responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Relatedly, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled “User Fees for 513(g) Requests for Information; Guidance for Industry and Food and Drug Administration Staff”<sup>2</sup> assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910-0511.

In the **Federal Register** of January 13, 2021 (86 FR 2674), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received five comments; however, the comments

<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic>.

<sup>2</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information>.

were not responsive to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Devices and Radiological Health 513(g) requests .....	114	1	114	12	1,368
Center for Biologics Evaluation and Research 513(g) requests .....	4	1	4	12	48
Total .....					1,416

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 26, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-09624 Filed 5-6-21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-N-0336]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘Healthy’ on Packaged Foods**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a new collection of information for a study entitled “Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘Healthy’ on Packaged Foods.”

**DATES:** Submit either electronic or written comments on the collection of information by July 6, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before July 6, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 6, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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-2021-N-0336 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘Healthy’ on Packaged Foods.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.” The Agency will review this copy, including the claimed confidential information, in its 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