

the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551-0001, not later than April 21, 2021.

A. *Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Blake Schultz, Norwalk, Iowa, Sarah Schultz Freiling, Monona, Iowa, and Stephanie Schultz Steele, Luana, Iowa*; together with David Schultz, Luana, Iowa, previously approved, to form the Schultz Family Control Group, a group acting in concert, to retain voting shares of Luana Bancorporation, and thereby indirectly retain voting shares of Luana Savings Bank, both of Luana, Iowa.

Board of Governors of the Federal Reserve System, March 31, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-07011 Filed 4-5-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement for the National Association of Area Agencies on Aging

AGENCY: Community Living Administration, Department of Health and Human Services.

ACTION: Announcing the intent to award a single-source supplement for the National Association of Area Agencies on Aging for the Eldercare Locator cooperative agreement.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Area Agencies on Aging for the Eldercare Locator. Older adults are at greater risk of requiring hospitalization or dying if diagnosed with COVID-19, therefore ensuring that this population is vaccinated is an imperative. In addition, we recognize that the COVID-19 pandemic has birthed many challenges for people with disabilities and linking this population to vaccination resources is also critically important. The purpose of this project is to increase the capacity of the current Eldercare Locator call center to assist additional older adults in obtaining information and linkages to state and local organizations for the purpose of

obtaining COVID-19 vaccines. In addition, utilizing the Eldercare Locator platform to develop a call center to assist people with disabilities with state and local resources to obtain links to vaccines and community resources.

Program Name: The Eldercare Locator.

Recipient: The National Association of Area Agencies on Aging.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of June 1, 2018, through May 31, 2023.

Total Award Amount: \$5,140,000 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 National Association of Area Agencies on Aging is currently funded to carry out the objectives of this program, entitled The Eldercare Locator. Older adults and their caregivers face a complicated array of decisions regarding home and community-based services. For almost 30 years, the Eldercare Locator has helped older adults and their families navigate this complex environment by connecting those needing assistance with State and local agencies on aging that serve older adults and their caregivers. The Eldercare Locator serves approximately 450,000 people a year through the call center. To ensure that the needs of those who contact the Eldercare Locator are carefully matched with the appropriate resources, information specialists are trained to listen closely to callers, identify relevant local, state and/or national resources and, when needed, provide a transfer to a particular resource.

As a trusted national resource, the supplement to the Eldercare Locator will be used to expand the capacity of the service to link a larger number of older adults and their caregivers seeking COVID-19 vaccines with local organizations that can assist in making the appropriate connections and appointments. With the supplemental funding, ACL will fund the expansion of the Eldercare Locator Call Center to support an increase of 500,000 calls from older adults and their caregivers. In addition, the Call Center will utilize and maintain a list of trusted resources, such as the CDC Vaccine Finder, to assist callers in making appropriate local COVID-19 vaccine connections.

Some people with disabilities might be at a higher risk of COVID-19 infection or severe illness because of their underlying medical conditions. Having to sift through countless

websites and make multiple phone calls to gain education and access to vaccine resources is a significant issue. Having a one-stop call center quickly set-up to provide accurate and up-to-date state and local specific information and referrals regarding COVID-19 vaccines and information regarding local community resources for people with disabilities is critically needed. Using the established Eldercare Locator infrastructure, this supplement will be used for the rapid development of a call center to assist people with disabilities to make appropriate state and local linkages to COVID-19 vaccines and other resources. The grantee, working with appropriate national disability organizations, will establish a call center with a dedicated line and trained information specialists to serve approximately 500,000 people with disabilities.

For More Information Contact: For further information or comments regarding this program supplement, contact Sherri Clark, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging (202)-795-7327; email Sherri.Clark@acl.hhs.gov.

Dated: March 31, 2021.

Alison Barkoff,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2021-06999 Filed 4-5-21; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, 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 May 6, 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 0910–0792. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@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.

Food Allergen Labeling and Reporting
OMB Control Number 0910–0792—Extension

This information collection supports the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens, and the Agency’s associated guidance document.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining the term “major food allergen” and stating that foods regulated under the

FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines a major food allergen as “[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans” and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(6) of the FD&C Act).

Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient “does not contain allergenic protein” or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(7) of the FD&C Act).

Description of Respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States that declare the presence of a major food allergen on the product label. In terms of reporting, the respondents are manufacturers and packers of packaged foods sold in the United States that seek an exemption from the labeling requirements of section 403(w)(1) of the FD&C Act.

In the **Federal Register** of October 28, 2020 (85 FR 68333), we published a 60-day notice requesting public comment on the proposed collection of information. Although some comments were received, they pertained to substantive and/or technical aspects of statutory requirements found in section 403(w) of the FD&C Act, or recommendations found in related Agency guidance. None of the comments discussed the information collection topics found in 5 CFR 1320.5(a)(1)(B) as requested in the notice, nor did any of the comments suggest FDA revise its estimate of the burden for the information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

FD&C Section; Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500
403(w)(1); redesign labels to comply with food allergen labeling requirements	1	1	1	16	16
Total					77,516

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

A. Third-Party Disclosure

The labeling requirements of section 403(w)(1) of the FD&C Act apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. As

noted, section 403(w)(1) of the FD&C Act requires that the label of a food product declare the presence of each major food allergen. We estimate the information collection burden of the third-party disclosure associated with food allergen labeling under section 403(w)(1) of the FD&C Act as the time

needed for a manufacturer to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act and the time needed to make any needed modifications to the labels of those products. The allergen information disclosed on the label or labeling of a

food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers use food labeling information to help determine their product choices.

Based on a review of the information collection since our last request for

OMB approval, we are decreasing our burden estimate for the redesign of labels. FALCPA was enacted in 2004, and we issued associated Agency guidance in 2015. Firms have had substantial time to redesign their labels for compliance with section 403(w) of the FD&C Act. We do not anticipate any firms needing to redesign their label to

come into compliance with section 403(w)(1) of the FD&C Act. Thus, we are decreasing the number of respondents redesigning their label from 3,875 to 1 and the number of hours from 62,000 to 16. We estimate one respondent for the purpose of maintaining this information collection provision.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

FD&C Section; Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

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

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, respondents may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(6) of the FD&C Act). This section also states that “the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.” Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient “does not contain allergenic protein” or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(7) of the FD&C Act).

We issued a guidance document entitled “Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications,” which is available on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications>. The guidance sets forth our recommendations with regard to the information that respondents should

submit in such a petition or notification. The guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes: (1) The identity or composition of the ingredient; (2) the methods used to produce the ingredient; (3) the methods used to characterize the ingredient; (4) the intended use of the ingredient in food; and (5) either (a) for a petition, data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient, when manufactured and used as described, does not cause an allergic response that poses a risk to human health; or (b) for a notification, data, and information that demonstrate that the ingredient, when manufactured as described, does not contain allergenic protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-07002 Filed 4-5-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS 4040-0018]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 7, 2021.

ADDRESSES: Submit your comments to Ed.Calimag@hhs.gov or (202) 690-7569.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040-0018-60D and project title for reference to Ed.Calimag@hhs.gov, or call (202) 690-7569, the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.