1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

In the FR Doc. 2014–13863 of June 13, 2014 (79 FR 33927), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled ''Medicare Part C and Part D Data Validation.'' There were technical delays with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the June 13, 2014, notice.

Dated: August 7, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–19027 Filed 8–11–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the 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 invites comments on the information collection provisions of the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the information collection provisions of the draft guidance entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.''

DATES: Submit either electronic or written comments on the collection of information by October 14, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Food Allergen Labeling and Reporting—(OMB Control Number 0910–NEW)

I. Background

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108–282) amended the 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 (21 U.S.C. 343(w)(6)). 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 (21 U.S.C. 343(w)(7)).

In the **Federal Register** of May 8, 2014 (79 FR 26435), we published a notice of availability for the draft guidance document entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.'' This draft guidance is intended to help industry prepare petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens. Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances.*

II. Analysis of the Proposed Information Collection

The proposed information collection seeks OMB approval of the third party disclosure requirements of food allergen labeling under section 403(w)(1) of the FD&C Act, as well as OMB approval of the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens under section 403(w)(6) and (7) of the FD&C Act.

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 primary user of the allergen information disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to help them make choices concerning their purchase of a food product, including choices related to substances that the consumer wishes to avoid due to their potential to cause adverse reactions. Additionally, we intend to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403(w)(1) of the FD&C Act may result in a product being misbranded under the FD&C Act and the manufacturer or packer and the product subject to regulatory action.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States.

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

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

FD&C Act section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Avg. burden per disclosure	Total hours	Total capital costs
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500	0
403(w)(1); redesign labels to comply with food allergen labeling requirements	3,875	1	3,875	16	62,000	$7,071,875
Total					139,500	$7,071,875

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

We used our labeling cost model (Ref. 1) to estimate the number of new or reformulated products sold in the United States, annually, that are affected by the requirements of section 403(w)(1) of the FD&C Act. We estimate that there are approximately 690,000 Universal Product Codes (UPCs) of FDA-regulated foods and approximately 85,000 UPCs of FDA-regulated dietary supplements for a total of 775,000 UPCs (Ref. 1). Using our labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 × 10 percent). Thus, we estimate that, annually, 77,500 new or reformulated products are sold in the United States. Assuming an association of one respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify the need to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 5 percent of the reviewed labels of new or reformulated products, or 3,875 labels (77,500 × 5 percent) would need to be redesigned to comply with the requirements of section 403(w)(1) of the FD&C Act. Assuming an association of one respondent to each of the 3,875 labels, we estimate that 3,875 respondents will each redesign one label, as reported in table 1, row 2.

Our estimate of the average burdens per disclosure reported in table 1 is based on our experience with food labeling and our labeling cost model. We estimate the average burden for the review of labels for compliance with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act to be 1 hour. Consequently, the burden of reviewing the labels of new or reformulated products is 77,500 hours, as reported in table 1. Using our labeling cost model, we estimate that it takes an average of 16 hours to complete the administration and internal design work for the redesign of a label to comply with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act. Consequently, the burden of redesigning the 3,875 labels of new or reformulated products is 62,000 hours, as reported in table 1.

Using our labeling cost model, we estimate the capital cost to be $1,825 per label for external design services for the redesign of a label. Consequently for 3,875 labels, the total capital costs are $7,071,875 (3,875 labels × $1,825 per label), as reported in table 1.

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, interested parties 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).

Our draft guidance document entitled, ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications,'' sets forth our recommendations with regard to the information that an interested party should submit in such a petition or notification. The draft 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 either

5. 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

5. 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 will use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of sections 403(w)(6) and (7) of the FD&C Act for granting the exemption.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States that seek an exemption from the labeling requirement of section 403(w)(1) of the FD&C Act.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section	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.

Based on the number of petitions and notifications received in recent years, we estimate that we will receive an average of five petitions and five notifications annually, over the next 3 years. Assuming an association of one respondent to each petition or notification, we estimate that five respondents will each submit one petition and five respondents will each submit one notification, as reported in table 2, rows 1 and 2.

We base our estimate of the average burdens per response reported in table 2 on our experience with other petition processes. We estimate that a petition would take, on average, 100 hours to develop and submit (Ref. 2). Therefore, we estimate that the burden associated with petitions will be 500 hours annually (5 petitions $\times$ 100 hours per petition).

The burden of a notification involves collecting documentation that a food ingredient does not pose an allergen risk. Either we can make a determination that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409 of the FD&C Act, or the respondent would submit scientific evidence demonstrating that the ingredient when manufactured as described does not contain allergenic protein. We estimate that it would take a respondent 20 hours to prepare and submit a notification based on our determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response. We estimate that it would take a respondent approximately 100 hours to prepare a notification submitting scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein. We have no data on how many notifications would be based on our determination that the ingredient does not cause an allergic response or based on scientific evidence that demonstrates that the food ingredient does not contain allergenic protein. Therefore, we estimate that three of the five notifications would be based on scientific evidence, and two of the five notifications would be based on our determination. The average time per notification is then estimated to be 68 hours (2×20 hours + 3×100 hours)/5). Therefore, we estimate that the burden associated with notifications will be 340 hours annually (5 notifications $\times$ 68 hours per notification), as reported in table 2.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. RTI International. ''Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Final

Report.'' Prepared for Andrew Stivers, FDA/CFSAN. Prepared by Muth, M., M. Ball, M. Coglaiti, and S. Karns. RTI Project Number 0211460.005. March, 2011.

2. Gendel, Steven M. ''Food Allergen Petitions and Notifications,'' Memorandum to File. August 8, 2011.

Dated: August 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19004 Filed 8–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Allergy and Infectious Diseases Special Emphasis Panel NIAID Peer Review Meeting.

Date: September 4, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 3130, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Roberta Binder, Ph.D., Scientific Review Officer, Scientific, Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892–7616, 301–496–7966, *rbinder@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel ''NIAID Investigator Initiated Program Project Applications (P01).''

Date: September 17, 2014.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3120, 6700B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–402–3938, *lr228v@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 6, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–18991 Filed 8–11–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Retroviral Pathogenesis, Treatment and Prevention.

Date: September 11, 2014.

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

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 5W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Scientific Review Officer, Research Technology and Contract Review, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W102, Bethesda, MD 20892–8329, 240–276–6341, *vollbergt@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 6, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–18997 Filed 8–11–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: National Advisory Mental Health Council.

Date: September 18, 2014.

Open: 8:30 a.m. to 12:30 p.m.

Agenda: Presentation of NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health (NIH), Neuroscience Center, Conference Rooms C/D/E, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, Conference Rooms C/D/E, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jane A. Steinberg, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–5047.