information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28789 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by December 14, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0642. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910–0642)–Extension

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of September 1, 2009 (74 FR 45221), we announced the availability of a guidance document entitled, ''Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance document contains questions and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides our interpretation of the labeling requirements for section 403(y) of the FD&C Act and our views on the information that should be included on the label. We believe that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

In the **Federal Register** of August 24, 2015 (80 FR 51278), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,700	3.27	5,560	0.2	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,700	3.27	5,560	0.2	1,112
Total					2,224

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

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although we exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, we expect that all labels required to include the domestic address or telephone number issued in section 403(y) have been revised accordingly. Thus our current burden estimate for this information collection applies only to new product labels.

In row 1 of Table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act (21 U.S.C. 343(y)) to be 1,112 hours. Using historical A.C. Nielson Sales Scanner Data, we estimate the number of dietary supplement SKUs for which product sales are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year approximately 5,560 new dietary supplement products are projected to enter the market. Estimating that there are 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as

provided in our final rule of June 25, 2007 (72 FR 34752) on the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, and factoring for a two percent annual growth rate), we calculate an annual disclosure burden of 3.27 disclosures (labels) per firm. Last, we expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed and therefore believe that less than 0.2 hours (12 minutes) per product label would be expended to fulfill this requirement.

In row 2 of Table 1 we estimate the total burden associated with the recommendation to include an explanatory statement on dietary supplement product labels letting consumers know the purpose of the domestic address or telephone number to be 1,112 hours. Based upon our knowledge of food and dietary supplement labeling, we estimate it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28788 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Battelle King Avenue Site in Columbus, Ohio, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice of a decision to evaluate a petition to designate a class of employees from the Battelle King Avenue site in Columbus, Ohio, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 CFR 83.9–83.12.

Pursuant to 42 CFR 83.12, the initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Battelle King Avenue.

Location: Columbus, Ohio.

Job Titles and/or Job Duties: All Atomic Weapons Employees who worked at the facility owned by the Battelle Laboratories at the King Avenue site in Columbus, Ohio, during the period from July 1, 1956 through December 31, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

Period of Employment: July 1, 1956 through December 31, 1970.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2015–28905 Filed 11–12–15; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

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

The meeting will be open to the public, 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.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 10–11, 2015.

Time: December 10, 2015, 9:00 a.m. to 5:00 p.m.

Agenda: NIH Director's report and ACD Working Group reports.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Time: December 11, 2015, 9:00 a.m. to Adjournment

Agenda: IC Director reports and any other committee business.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 6, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28797 Filed 11–12–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Aging; 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 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.