II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in investigational new drug applications is approved under OMB control number 0910–0014; the collection of information (including prescription drug labeling) in new drug applications and abbreviated new drug applications, as well as supplements to these applications, is approved under OMB control number 0910–0001; the collection of biologics license applications is approved under OMB control number 0910–0338; and the format and content of prescription drug labeling is approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14354 Filed 6–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0717]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

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 July 18, 2016.

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 0910–0753. 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.

Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns—OMB Control Number 0910–0753—Revision

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages; and whether campaign exposure influences beliefs about tobacco, susceptibility to tobacco use, and tobacco use behavior. All of the information collected is integral to that evaluation.

FDA is in the process of conducting three studies to evaluate the effectiveness of its youth tobacco prevention campaigns: (1) An outcome evaluation study of its General Market Youth Tobacco Prevention Campaign, (2) an outcome evaluation of the Rural Male Youth Smokeless Tobacco Campaign, and (3) a media tracking survey. The timing of these studies follows the multiple, discrete waves of media advertising planned for the campaigns.

Evaluation of the General Market Youth Tobacco Prevention Campaign

The General Market Youth Tobacco Prevention Campaign targets youth who are at-risk for smoking, or who have experimented with but not progressed to regular smoking. The outcome evaluation of the campaign consists of an initial baseline survey of youth aged 11 to 16 before campaigns launch, followed by a number of longitudinal follow-up surveys of the same youth at approximate 8 month intervals. To date, the baseline and three follow-up surveys have been conducted. A baseline survey was also conducted with the parent or legal guardian of each youth, to collect data on household characteristics and media use. Because the cohort aged over the study period, data have been collected from youth aged 11 to 18. Information has been collected about youth awareness of and exposure to campaign advertisements and about youth knowledge, attitudes, and beliefs related to tobacco use. In addition, the surveys have measured tobacco use susceptibility and current use. Information has been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

Evaluation of the Rural Male Youth Smokeless Tobacco Campaign

Baseline data collection for the Rural Male Youth Smokeless Campaign evaluation will begin in January 2016. The three follow up surveys will begin in August 2016, March 2017, and October 2017. The evaluation of the Rural Male Youth Smokeless Campaign differs from the General Market Campaign evaluation, in that only males in the age range will be considered eligible.

Media Tracking Survey

The media tracking survey consists of assessments of youth aged 13 to 18 conducted periodically during the campaign period. The tracking survey assesses awareness of the campaign and

receptivity to campaign messages. These data provide critical evaluation feedback to the campaigns and are conducted with sufficient frequency to match the cyclical patterns of media advertising and variation in exposure to allow for mid-campaign refinements.

All information is being collected through in-person and web-based questionnaires. Youth respondents were recruited from two sources: (1) A probability sample drawn from 90 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluations, and (2) an Internet panel for the media tracking survey. Participation in the studies is voluntary.

The studies are being conducted in support of the provisions of the Tobacco Control Act, which require FDA to protect the public health and to reduce tobacco use by minors. The information being collected is necessary to inform FDA's efforts towards those goals and to measure the effectiveness and public health impact of the campaigns. Data from the outcome evaluation of the General Market and Rural Male Youth Smokeless campaigns is being used to examine statistical associations between exposure to the campaigns and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, beliefs, and intentions related to tobacco use, as well as behavioral outcomes including tobacco use. Data from the media tracking survey is being used to estimate awareness of and exposure to the campaigns among youth nationally as well as among youth in geographic areas targeted by the campaign.

FDA requests OMB approval to collect additional information for the purpose of extending the evaluation of FDA's general market youth tobacco prevention campaign. Specifically, FDA requests approval to conduct a fourth follow-up survey with youth who are part of the first longitudinal cohort, and who participated in the baseline and first through third follow-up surveys. Based on earlier response rates, we estimate that 1,607 will participate in this survey, for a total of 6,666 annualized participants (including 5,059 previously approved). At 0.75 hours per survey, this adds 1,205 annualized burden hours to the 3,794 previously approved hours for a total of 5,000 annualized burden hours. Baseline data collection for this cohort, approved for 2,288 participants (1,144 burden hours at 30 minutes per survey) is complete.

FDA also requests approval to develop and survey a second longitudinal cohort which will consist of an entirely new sample of youth, ages 11–16 at baseline. Development of the second cohort will involve screening 17,467 individuals in the general population for a total of 30,880 participants, including 13,413 previously approved. At 10 minutes per screening, this adds 2,970 burden hours to the already approved 2,280 hours for a total of 5,250 annualized burden hours.

We expect this screening to yield 2,667 youth annually who will complete the baseline survey for the new cohort at 45 minutes per survey, resulting in a total of 2,000 burden hours for youth. Three follow up surveys are planned for this cohort. We expect a total of 6,270 participants to complete follow up surveys for a total burden of 4,703 annualized burden hours. As was done with the first cohort, parents of the 2,667 youth will also complete surveys for a total of 6,009 parent surveys including the 3,342 previously approved. At 10 minutes per survey, this adds 453 hours to the previously approved 568 hours for a total of 1,021 annualized burden hours.

FDA also requests approval to extend the media tracking survey. This survey is cross sectional and thus necessitates brief screening prior to data collection. We expect 20,000 participants to complete screener for a total of 60,000 participants (including 40,000 previously approved). At 2 minutes per screener, this adds 600 burden hours to the previously approved 1,200 hours for a total of 1,800 annualized burden hours. We expect the screening process to yield 2,000 participants, for a total of 6,000 including 4,000 previously approved. At 30 minutes per survey, this adds 1,000 burden hours to the already-approved 2,000 for a total of 3,000 annualized burden hours.

FDA also requests approval to extend the time period of the evaluation of the Male Rural Youth Smokeless Campaign. No new burden hours will be required to complete this study. Previously approved burden for the evaluation of the Rural Male Youth Smokeless Campaign include 656 annualized participants (328 annualized burden hours at 30 minutes per questionnaire) for the baseline questionnaire and 1,281 annualized participants (961 annualized burden hours at 0.75 hours per questionnaire).

In the **Federal Register** of February 19, 2016 (81 FR 8511), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Two burden items have been revised since the publication of the 60-day notice. First, number of respondents planned for the General Population Screener and Consent Process has been corrected to annualize the new screening participants over the 3-year extension. Second, the burden per response for the Cohort 2 Youth Baseline has been increased to 45 minutes to better reflect the actual time required for completion as assessed during the previous data collection rounds.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General Population	Screener and Consent Process (Youth and Parent).	30,880	1	30,880	0.17 (10 minutes)	5,250
Parent of Youth Baseline Survey Participants.	Parent Baseline Questionnaire	6,009	1	6,009	0.17 (10 minutes)	1,022
Youth Aged 11 to 18 (Experimenters and Non-Triers).	Youth Baseline Questionnaire (Experimenters & Non-Triers).	2,288	1	2,288	0.50 (30 minutes)	1,144
	Youth 1st, 2nd, 3rd, 4th Follow-up Questionnaire (Experimenters and Non-Triers)	6,666	1	6,666	0.75 (45 minutes)	5,000
Youth Aged 13 to 17	Media Tracking Screener	60,000	1	60,000	0.03 (2 minutes)	1,800
	Media Tracking Questionnaires 1st, 2nd, and 3rd	6,000	1	6,000	0.50 (30 minutes)	3,000

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Male Youth Aged 11 to 18 in U.S. Rural Markets (Male Rural Smokeless).	Youth Baseline Questionnaire (Male Rural Smokeless).	656	1	656	0.50 (30 minutes)	328
	Youth 1st, 2nd, 3rd (Male, Rural Smokeless) Follow-up Questionnaire	1,281	1	1,281	0.75 (45 minutes)	961
Cohort 2—Youth Aged 11 to 18	Cohort 2—Youth Baseline Questionnaire.	2,667	1	2,667	0.75 (45 minutes)	2,000
	Cohort 2—Youth 1st, 2nd, 3rd Follow-Up Questionnaire	6,270	1	6,270	0.75 (45 minutes)	4,703
Total				122,717		25,208

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

Dated: June 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14352 Filed 6–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to 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 (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Idaho National Laboratory site in Scoville, Idaho, as an addition to the Special Exposure Cohort (SEC) 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, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

On June 3, 2016, as provided for under 42 U.S.C. 7384*l*(14)(C),the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Idaho National Laboratory (INL) in Scoville, Idaho, and were monitored for external radiation at INL (*e.g.,* having at least one film badge or TLD dosimeter) during the period from March 1, 1970, through December 31, 1974, and were employed for a number of work days aggregating at least 250 work days, occurring either solely under employment during the period from March 1, 1970, through December 31, 1974, or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

This designation will become effective on July 3, 2016, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2016–14327 Filed 6–16–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to 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 (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Lawrence Livermore National Laboratory site in Livermore, California, as an addition to the Special Exposure Cohort (SEC) 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, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On June 3, 2016, as provided for under 42 U.S.C. 73841(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at the Lawrence Livermore National Laboratory in Livermore, California, during the period from January 1, 1974, through December 31, 1989, 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.

This designation will become effective on July 3, 2016, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2016–14326 Filed 6–16–16; 8:45 am]

BILLING CODE 4163–19–P