each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). The total amount of user fees to be collected for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) FDA is to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total assessment to be allocated among the classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco product removed into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market for that tobacco product class.

In the **Federal Register** of September 11, 2018 (83 FR 45937), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was not PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1150.5(a), (b)(1) and (2), and Form FDA 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	658	12	7,896	3	23,688
1150.5(b)(3); Certified copies (monthly)	658	12	7,896	1	7,896
1150.13; Submission of user fee information (identifying information, fee amount, etc.) (quarterly)	329	4	1,316	1	1,316
1150.15(a); Submission of user fee dispute (annually)	5	1	5	10	50
1150.15(d); Submission of request for further review of dispute of user fee (annually)	3	1	3	10	30
Total					32,980

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

FDA estimates that 658 entities will submit tobacco product user fees. The entity count was derived from aggregate data provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB), and reflects that in 2017 there were 192 total permitted manufacturers and 466 permitted importers over all tobacco product types for which TTB collects excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco, excluding electronic nicotine delivery systems).

The estimate of 658 respondents to provide the information requested from § 1150.5(a), (b)(1) and (2) (21 CFR 1150.5(a), (b)(1) and (2)), and Form FDA 3852 reflects both reports of no removal of tobacco products into domestic commerce and reports of removal of tobacco product into domestic commerce. FDA estimates it will take 3 hours for each of these submission types for a total of 23,688 hours. Under § 1150.5(b)(3), these respondents are also expected to provide monthly certified copies of the returns and forms that relate to the removal of tobacco products into domestic commerce and the payment of Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986 to FDA. We estimate that each monthly report will take 1 hour for a total of 7,896 hours. The estimate of 329 respondents to submit payment of user fee information under § 1150.13 reflects an average of half the number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA estimates the quarterly submission will take approximately 1 hour for a total of 1,316 hours.

FDA estimates that five of those respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total amount of 50 hours. FDA also estimates that three respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 30 hours. FDA has only received one dispute submission since fiscal year 2015. Based on this data, the Agency does not believe we will receive more than five disputes and three requests for further reviews in the next 3 years.

FDA estimates the total annual burden for this collection of information is 32,980 hours. The estimated burden for the information collection reflects an overall increase of 16,058 hours. We attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10287 Filed 5–16–19; 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; Proposed Collection; 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 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the evaluation of FDA's General Market Youth Tobacco Prevention Campaigns.

DATES: Submit either electronic or written comments on the collection of information by July 16, 2019.

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 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 16, 2019. 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. Insert docket number FDA–2013–N–0717 for ''Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns.'' 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.

- 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 ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

OMB Control Number 0910–0753—Extension

Rationale for and Overview of the Evaluation Studies

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (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 the information collected is integral to that evaluation.

FDA is 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. The outcome evaluation of the smokeless tobacco campaign is now complete, while the other two studies are ongoing.

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 smoking but not progressed to regular smoking. The campaign evaluation consists of surveys conducted with two cohorts of youth and their parents or guardians. Each cohort consists of an initial baseline survey of youth aged 11 to 16, and followup surveys of the same youth at approximate 8-month intervals. At baseline, surveys are also conducted with the parent or legal guardian of each youth, to collect data on household characteristics and media use. Because youth age over the study period, the age range of youth and young adults among whom we collect data over the study period are aged 11 to 18.

Data collection associated with the first cohort, including a baseline survey and four followup surveys, is complete. We have also completed baseline data collection for the second cohort. We are planning three followup surveys of youth in the second cohort.

The Rural Male Youth Smokeless Tobacco Campaign

The Rural Male Youth Smokeless Campaign is also a longitudinal study. Baseline data for this evaluation were collected in January 2016. Followup surveys were conducted in September 2016, May 2017, January 2018, and September 2018. This portion of the study is now complete.

Media Tracking Survey

The Media Tracking Survey consists of assessments of youth aged 13 to 17 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.

Methods Used for the Evaluation Studies

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.

Purpose of the Evaluation Studies

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 are being used to examine statistical associations between exposure to the campaigns and subsequent changes in specific outcomes of interest, which include knowledge, attitudes, beliefs, and intentions related to tobacco use, as well as behavioral outcomes including tobacco use. Data from the media tracking survey are 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.

Request To Collect Information for the Evaluation

FDA requests an extension of the study OMB control number 0910–0753 to continue collecting data for the General Market outcome evaluation. No additional burden is requested for this portion of the information collection. FDA also requests approval for additional burden for the Media Tracking Survey. This is 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 80,000 participants (including 60,000 previously approved). At 2 minutes per screener, this adds 600 burden hours to the previously approved 1,800 hours for a total of 2,400 annualized burden hours. We expect the screening process to yield 2,000 participants, for a total of 8,000 including 6,000 previously approved. At 30 minutes per survey, this adds 1,000 burden hours to the already-approved 3,000 for a total of 4,000 annualized burden hours.

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).	17,467	1	17,467	0.17 (10 minutes) ..	2,969
Parent of Youth Baseline Survey Participants.	Parent Baseline Questionnaire.	2,667	1	2,667	0.17 (10 minutes) ..	453
Youth Aged 13 to 17	Media Tracking Screener	80,000	1	80,000	0.03 (2 minutes)	2,400
	Media Tracking Questionnaires 1st, 2nd, and 3rd.	8,000	1	8,000	0.5 (30 minutes)	4,000

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
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 Followup Questionnaire.	6,270	1	6,270	0.75 (45 minutes) ..	4,703
Totals	.....	.....	.....	.....	.....	16,525

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

To accommodate the additional data collection for media tracking, FDA requests approval to increase the number of burden hours under the existing control number. The previous number of approved screener responses for media tracking was 60,000 and the associated burden was 1,800 hours. The previous burden for the media tracking questionnaires was 6,000 and the associated burden was 3,000 hours. We are requesting an additional 20,000 screener responses and 2,000 questionnaire completions, which adds 600 burden hours and 1,000 burden hours respectively. Deducting the responses and burden for the completed evaluation components associated with Cohort 1 (general population screening (13,413 responses, 2,281 hours), parent interviews (3,342 responses, 569 hours), youth questionnaires (8,954 responses, 6,144 hours)) and for the rural smokeless evaluation (2,610 responses, 1,794 hours) results in a decrease of 6,319 annual responses and 9,187 hours.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10320 Filed 5–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Council of Research Advocates, May 20, 2019, 9:30 a.m. to 4:00 p.m., National Institutes of Health, Building 40, Room 1201/1203, 40 Convent Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 11, 2019, 84 FR 14662.

This meeting notice is amended to change the meeting start time from 9:00 a.m. to 9:30 a.m. on May 20, 2019 at the National Institutes of Health, Building 40, Room 1201/1203, 40 Convent Drive, Bethesda, MD 20892. This meeting is open to the public.

Dated: May 13, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–10217 Filed 5–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Resources for Technology Dissemination (U24) Review Meeting (2019/08).

Date: June 27, 2019.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging, and Bioengineering, National Institutes of Health, Two Democracy Boulevard, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20892, 301–451–4794, *dennis.hlasta@nih.gov.*

Dated: May 13, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–10235 Filed 5–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

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 Council on Alcohol Abuse and Alcoholism.

Date: June 6, 2019.

Time: 1:30 p.m. to 2:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 1206, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Advisory Council, Director, Office of Extramural Activities, National Institute On Alcohol Abuse And Alcoholism, 6700 B