TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 U.S.C. section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Dietary supplement adverse event records (21 U.S.C. 379aa–1(e)(1)).	1,700	74	125,800	0.5 (30 minutes)	62,900

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

All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event recordkeeping. We estimate that there are 1,700 such respondents, based on the figure 1,460 as provided in our final rule of June 25, 2007 (72 FR 34751) on the ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,'' and factoring a two percent annual growth rate. Estimating that each recordkeeper will keep approximately 74 records per year results in an annual burden of 125,800 records. Estimating that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hours, per record, results in an annual burden of 62,900 hours (125,800 records × 0.50 hours = 62,900 total hours.

Once the documents pertaining to an adverse event report have been assembled and filed in accordance with the safety reporting portal, we expect the records retention burden to be minimal, as we believe most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26673 Filed 10–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2126]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's Campaign To Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults

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 November 20, 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 title ''Evaluation of the Food and Drug Administration's Campaign to Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults''. 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 Campaign To Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults—OMB Control Number 0910—New

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended 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 public education campaigns to help prevent and reduce tobacco use among lesbian, gay, bisexual, and transgender (LGBT) young adults and thereby reduce the public health burden of tobacco. Overall the campaigns will feature events; advertisements on television and radio and in print; digital communications including social media; and other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use, FDA requests OMB approval to collect information needed to evaluate FDA's campaign to reduce tobacco use among LGBT young adults. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to conduct two studies to evaluate the effectiveness of its LGBT young adult tobacco prevention campaign: (1) An outcome evaluation study to evaluate the effectiveness of its LGBT young adult tobacco prevention campaign, and (2) a media tracking questionnaire to assess awareness of and receptivity to campaign messages. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

I. Outcome Evaluation Study

Before the beginning of data collection for the outcome evaluation study, the 5-minute screening instrument will be tested in a small pilot study of LGBT young adults aged 18 to 24. The outcome evaluation study will then begin with a baseline survey of LGBT young adults aged 18 to 24 before the campaign launch. The baseline will be followed by three followup surveys of the target audience of young adults at approximately 6-month intervals after the campaign's launch. Information will be collected

about young adult awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions and use, as well as use of other tobacco products (e-cigarettes, hookah, cigars, smokeless tobacco), marijuana and alcohol. Information will also be collected on demographic variables including sexual orientation, age, sex, race/ethnicity, education, and primary language.

All information will be collected through in-person and Web-based questionnaires. Young adult respondents will be recruited in 24 U.S. cities (12 campaign and 12 comparison cities) from two sources: (1) Intercept surveys in LGBT social venues (*e.g.,* bars and nightclubs) and (2) through social media advertisements (*e.g.* on Facebook and Twitter) targeted at LGBT 18 to 24-year-olds, living in the same 24 U.S. cities. Participation in the study is voluntary.

II. Media Tracking Survey

The media tracking survey consists of assessments of LGBT young adults aged 18 to 24 conducted in the periods in between the primary outcome evaluation survey waves to monitor the target audience's awareness of and receptivity to campaign activities. The media tracking survey will assess awareness of the campaign and receptivity to campaign messages. These data will provide critical evaluation feedback to the campaigns and will be conducted with sufficient frequency to match the cyclical patterns of events and media advertising and variation in exposure to allow for mid-campaign refinements. For the media tracking surveys, we will recruit LGBT young adults aged 18 to 24 from all campaign cities through social media.

The information collected is necessary to inform FDA's efforts and measure the effectiveness and public health impact of the campaigns. Data from the media tracking surveys will be used to estimate awareness of and exposure to the campaigns among young adults in target markets where the campaigns are active. Data from the outcome evaluation study will be used to examine statistical associations between awareness of and exposure to the campaigns and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, beliefs, and intentions related to tobacco use.

FDA's burden estimate is based on prior experience with in-person studies similar to the Agency's plan presented in this document, as well as previous research using social media advertising to recruit young adult participants. Since the 60-day notice was published, FDA has revised the estimated burden. The estimated burden has been revised to account for both participant eligibility and response rates among participants to be recruited via in-person intercept screening in LGBT bars and night clubs as only response rates were estimated in the 60-day notice. In addition, the burden table presented in this document now reports the annual burden estimate, which has been corrected from the 60-day notice, which reported total burden (rather than annual burden).

To reduce overall burden hours, participants who screen and complete the baseline outcome evaluation questionnaire will be re-contacted to complete the first followup campaign evaluation questionnaire; those who complete the first followup campaign evaluation questionnaire will be re-contacted to complete the second followup campaign evaluation questionnaire; and so on. Re-contacted individuals will not need to complete the screener again. We expect a 65 percent eligibility rate and 50 percent response rate for individuals recruited in person and a combined eligibility and response rate of 30 percent for individuals recruited via social media. In each successive round of data collection, we expect 50 percent of re-contacted individuals to complete the followup questionnaire; therefore, additional screenings will be conducted for each followup in order to maintain the target sample size for each followup questionnaire.

In-person recruitment will take place in a variety of LGBT venues (*e.g.,* bars, nightclubs). The owners or managers of potential recruitment sites will be asked a series of questions to determine the appropriateness of its clientele for participation in the study. Approximately 1,920 venues (640 annualized) will be assessed at 5 minutes per assessment for a total of 159 hours (53 annualized).

To obtain the target number of completed questionnaires (''completes'') for the outcome evaluation study, 24,744 (8,248 annualized, or annually over the 3-year approval period) young adults (18,177 (6,059 annualized) recruited in person and 6,567 (2,189 annualized) recruited via social media) will participate in a screening process (''screener''). The estimated burden per screener is 5 minutes (0.083 hour), for a total of 2,055 hours (685 annualized) (1,512 hours (504 annualized) for participants recruited in person and 543 hours (181 annualized) for persons recruited via social media). Before the beginning of data collection, the 5-minute screener will be tested in a small pilot study of 81 young adults (27 annualized) for a total of 6 hours (2 hours annualized).

A total of 12,612 (4,204 annualized) LGBT young adults (9,456 (3,152 annualized) of those screened in person and 3,156 (1,052 annualized) of those screened through social media) will complete questionnaires in four rounds of data collection (baseline and three post-campaign rounds). The estimated burden per complete is 30 minutes (0.5 hour) for the baseline questionnaire and 40 minutes (0.667 hour) for each followup complete, for a total of 7,884 hours (2,628 annualized) (5,916 hours (1,972 annualized) for those recruited in person and 1,968 hours (656 annualized) for those recruited via social media).

To obtain the target number of completes (1,503 completes (501 annualized)) for the media tracking survey, 5,004 (1,668 annualized) young adults will be recruited via social media ads to complete a screener for all three waves of the media tracking survey. The estimated burden per screener response is 5 minutes (0.083 hour), for a total of 415 (138 annualized) hours for all waves of media tracking screener. An estimated 501 (167 annualized) LGBT young adults will complete each of the three waves of the media tracking survey (assuming a 30 percent combined eligibility and response rate to screeners via social media). The estimated burden per completed media tracking questionnaire is 40 minutes (0.667 hour), for a total of 999 (333 annualized) hours for the three waves. The total burden for the media tracking survey (screeners and completes) is 1,413 hours (471 annualized).

The target number of completed campaign questionnaires (*i.e.,* screeners and questionnaires for both the outcome evaluation and media tracking survey) for all respondents is 45,864 (15,288 annualized). The total estimated burden is 11,517 (3,839 annualized).

In the **Federal Register** of June 30, 2015 (80 FR 37270), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments; however only one was PRA related.

(Comment) The commenter did not believe the amount of hours was justified for learning about the LGBT population. Additionally, the commenter did not see an explanation of the value of collecting this information.

(Response) FDA disagrees with this comment. The Tobacco Control Act

authorized FDA to develop and implement several public health education campaigns about the dangers of using tobacco products. Through literature reviews and analysis of national survey data, FDA identified groups that are uniquely at-risk of tobacco initiation due to a variety of factors, and who would benefit from an innovative education campaign designed to prevent tobacco use. One such group is young adults who identify as LGBT who, according to recent data, smoke at approximately two times the rate of the general adult population.

FDA is currently developing a national campaign targeting LGBT young adults ages 18–24 years. The purpose of the proposed study is to evaluate the campaign's reach and its effectiveness in changing their knowledge, beliefs, and attitudes regarding tobacco. FDA's public health education campaigns are a necessary and worthwhile investment to reduce the significant burden of tobacco use and ultimately make tobacco a part of America's past, not its future.

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 (in hours)	Total annual hours
Venue owners and managers.	Venue recruitment assessment.	640	1	640	0.083	53
Total Venue Recruitment.	.....	640	1	640	.....	53
General Population: Pilot test of recruitment social media recruitment.	Screener—Pilot study	27	1	27	0.083	2
Total Screener Pilot	.....	27	1	27	0.083	2
Screener: General population—Recruited in person (65% screen as eligible).	Screener—Baseline, outcome study.	2,423	1	2,423	0.083	201
	Screener—First followup, outcome study.	1,212	1	1,212	0.083	101
	Screener—Second followup, outcome study.	1,212	1	1,212	0.083	101
	Screener—Third followup, outcome study.	1,212	1	1,212	0.083	101
Screeners: In person	.....	6,059	.....	6,059	.....	504
Screener: General population—Recruited via social media.	Screener—Baseline, outcome study.	875	1	875	0.083	73
	Screener—First followup, outcome study.	438	1	438	0.083	36
	Screener—Second followup, outcome study.	438	1	438	0.083	36
	Screener—Third followup, outcome study.	438	1	438	0.083	36
Screeners: Social media	.....	2,189	.....	2,189	.....	181
Total screeners	.....	8,248	.....	8,248	.....	685
Outcome Study LGBT young adults aged 18–24 in select media markets—Recruited in person (50% response rate).	Questionnaire—Baseline outcome study.	788	1	788	0.5	394
	Questionnaire—First followup, outcome study.	788	1	788	0.667	526
	Questionnaire—Second followup, outcome study.	788	1	788	0.667	526
	Questionnaire—Third followup, outcome study.	788	1	788	0.667	526
Completes: Screened in person.	.....	3,152	.....	3,152	.....	1,972
Outcome Evaluation: LGBT young adults aged 18–24 in select media markets—Recruited via social media (30% combined eligibility and response rate).	Questionnaire—Baseline outcome study.	263	1	263	0.5	131
	Questionnaire—First followup, outcome study.	263	1	263	0.667	175
	Questionnaire—Second followup, outcome study.	263	1	263	0.667	175
	Questionnaire—Third followup, outcome study.	263	1	263	0.667	175
Completes: Recruited online	.....	1,052	.....	1,052	.....	656
Total completes (recruited in person and recruited online).	.....	4,204	.....	4,204	.....	2,628

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 (in hours)	Total annual hours
LGBT young adults aged 18–24 in the select media markets—Recruited via social media (30% combined eligibility and response rate).	Screener—First media tracking.	556	1	556	0.083	46
	Screener—Second media tracking.	556	1	556	0.083	46
	Screener—Third media tracking.	556	1	556	0.083	46
Media tracking screeners	.....	1,668	.....	1,668	.....	138
LGBT young adults aged 18–24 in the select media markets—Recruited via social media (30% combined eligibility and response rate).	Questionnaire—First media tracking.	167		167	0.667	111
	Questionnaire—Second media tracking.	167	1	167	0.667	111
	Questionnaire—Third media tracking.	167	1	167	0.667	111
Media tracking questionnaires.	.....	501	.....	501	.....	333
Total media tracking (screeners and questionnaires).	.....	2,169	.....	2,169	.....	471
Totals Across All Study Components.	.....	15,288	.....	15,288	.....	3,839

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

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26671 Filed 10–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3454]

Manufacturing Site Change Supplements: Content and Submission; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Manufacturing Site Change Supplements: Content and Submission''. This draft guidance describes the decision-making steps that FDA recommends to determine whether a premarket approval application (PMA) supplement should be submitted when a manufacturer intends to change the manufacturing site (including a change to the processing, packaging, or sterilization site) of its legally marketed PMA-approved device. This guidance also discusses the general factors FDA intends to consider to determine whether a preapproval inspection is necessary before approval of the PMA supplement. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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. FDA–2015–N–3454 for ''Manufacturing Site Change Supplements: Content and Submission.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.