As reflected in table 1, we estimate two manufacturers will submit two requests annually for tier-one DR, and that there will be one appeal of these requests to the DR panel (tier-two DR). We estimate also that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR, and approximately 8 hours to prepare and submit each request for a tier-two DR. Based on our experience with this collection we have not changed our estimate since our last request for OMB approval.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23444 Filed 10–26–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3710]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign

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 27, 2017.

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—NEW and title ''Evaluation of FDA's Education at the Point of Sale Campaign.'' Also, include the FDA docket number found in brackets in the heading of this document.

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: 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 Education at the Point of Sale Campaign OMB Control Number 0910—NEW

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 a tobacco education intervention at the point of sale to reduce the public health burden of tobacco use. The campaign features advertisements intended to encourage future quit attempts among current smokers in stores that sell tobacco products.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health, FDA requests OMB approval to collect information to evaluate the effectiveness of the point of sale tobacco education campaign. Data from this outcome evaluation study will be used to examine statistical associations between exposure to the campaign and specific outcomes of interest, which include awareness of the campaign and its messaging, tobacco-related attitudes, beliefs and risk perceptions, and motivation to quit smoking.

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 tobacco-related attitudes, beliefs and risk perceptions, intentions to use tobacco, and motivation to quit smoking. Participation in the outcome evaluation study will be voluntary. All of the information collected is integral to that evaluation.

Evaluation of the Point of Sale Campaign. This outcome evaluation study will consist of four longitudinal data collection periods over 24 months (approximately every 7 months), with the first survey (Wave 1) occurring approximately 3 months after campaign launch. A fourth wave of data collection has been added to the three proposed in the 60-day notice because the campaign has been extended from 18 to 24 months. The additional wave of data collection is necessary to continue to assess the impact of the campaign. To reduce the number of participants needed to detect the effects of the campaign on outcomes of interest, the design of the campaign was changed from two treatment groups and one control group to one treatment group and one control group. The respondent numbers and burden hours below have been revised to reflect the four data collection waves and the change in the number of treatment groups.

Information will be collected from adult cigarette smokers, ages 25 to 54, about awareness of and exposure to campaign advertisements, tobacco use, and knowledge, attitudes, and beliefs related to tobacco use. Information will be collected on demographic variables including age, sex, race/ethnicity, and primary language. Participants will also be offered the option to download a smartphone application that will track their exposure to the campaign, and that will ask them to respond to a brief survey about every 6 months over 18 months.

FDA's media contractor identified 37 potential counties for the campaign. From this list, FDA's evaluation contractor has selected 30 counties to be included in the evaluation. Of these, 15 counties will receive the intervention (treatment counties), and 15 counties will not receive it (control counties). The number of counties has changed since the 60-day notice because we changed the experimental design to have one treatment group instead of two, which resulted in needing fewer counties.

Data will be collected from a longitudinal cohort that will consist of an entirely new sample of adult cigarette smokers. Addresses will be randomly selected from postal carrier routes in the 30 selected U.S. counties to identify households that contain one or more adult smokers between the ages of 25 and 54. Pre-paid pre-addressed paper screening surveys will be mailed to approximately 104,541 households. We estimate that 27,651 (9,217 annualized respondents) households will return the 10-minute screener they received by mail, and 26,258 (8,753

annualized respondents) households will complete a 10-minute in-person field screener conducted by trained field interviewers. Field interviewers will attempt to conduct field screeners for all households that return the mail screener and appear to have one or more eligible participants in the household, and a subsample of the households that do not return the screener. At 10 minutes per screening, the potential burden hours for the mail screener are 4,701 hours (1,567 annualized). At 10 minutes per screening, the potential burden hours for the field screener are 4,464 hours (1,488). The process for locating and screening participants has been updated since the 60-day notice to better reflect the study design.

Accounting for nonresponse, we estimate that the mail and field screenings will result in 4,282 (1,427 annualized) adults who meet criteria for participation and complete the full Wave 1 questionnaire. The Wave 1 questionnaire will be completed during an in-person visit to the home, immediately after the field screening is completed, assuming the selected participant is available to complete the questionnaire at that time. If the participant is not available at that time, the interviewer will schedule a time to return to the household and complete the evaluation questionnaire in person. We estimate that the Wave 1 questionnaire will take 40 minutes to complete, resulting in 2,869 (956 annualized) burden hours. Adjusting for loss to follow-up between waves, we anticipate that 3,426 (1,142 annualized) participants will complete the Wave 2 questionnaire, which will take 40 minutes and result in 2,295 (765 annualized) burden hours, that 2,912 (971 annualized) participants will complete the Wave 3 questionnaire, which will take 40 minutes and result in 1,951 (650 annualized) burden hours, and that 2,475 (825 annualized) participants will complete the Wave 4 questionnaire, which will take 40 minutes and result in 1,658 (553 annualized) burden hours. The Waves 2, 3, and 4 questionnaires will be completed online or in person by trained interviewers, depending on participant preference. The total burden hours for Waves 2 to 4 evaluation questionnaires will be 5,904 (1,968 annualized).

We anticipate that approximately 54 percent of the participants (2,308 people (769 annualized)) who complete the Wave 1 questionnaire will download a smartphone application that will deliver brief app-based questionnaires to them in between the four waves of evaluation data collection. These participants will complete three questionnaires lasting 5 minutes each (every 6 months over the course of 18 months), resulting in 554 (185 annualized) burden hours. The app will also use geolocation technology to record participants' visits to convenience stores as a measure of passive campaign exposure.

In addition, over the course of the study, telephone verification questionnaires will be conducted with a small portion of participants. The purpose of these questionnaires is to ensure that information obtained by field interviewers is correct, to evaluate the performance of field interviewers, to avoid fraud, and to ensure that all relevant incentives were delivered. Trained staff will administer a 5-minute verification questionnaire to a random sample of 10 percent of participants who completed the in-person screening but not the Wave 1 questionnaire (2,198 individuals (733 annualized)), and a random sample of 10 percent of participants who completed the Waves 1 to 4 questionnaires (1,308 individuals (436 annualized)). At 5 minutes per verification questionnaire, this results in 177 burden hours (59 annualized) for the field screener telephone verifications and 105 burden hours (35 annualized) for the four evaluation questionnaire telephone verifications. Some telephone verification questionnaires may be administered in person if it is not possible to reach the individual by phone. This verification process has been added to the information collection request since the 60-day notice to prevent fraudulent data entry by interviewers.

In addition to the telephone verification survey, we will also audio record (with participants' consent) interviews with a random sample of approximately 10 percent of respondents to the Wave 1 questionnaire and a random 10 percent of the Waves 2, 3, and 4 respondents who complete the questionnaire in person as an additional quality control measure. These recordings will be used to measure interviewer compliance with study procedures and will be destroyed after they are reviewed. This procedure does not affect participant burden.

The total burden hours for the mail and field screeners, four outcome evaluation questionnaires, three app-based questionnaires, and four telephone verification questionnaires is 18,773 (6,258 annualized).

In the **Federal Register** of November 15, 2016 (81 FR 80075), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, only one was PRA-related.

Comment: One comment stated that requiring or compelling retailers to display ''anti-smoking or anti-tobacco advocacy'' is prohibited under the First Amendment. If the campaign is deemed unconstitutional, then there is no need for the information collection.

Response: The comment misunderstands how FDA intends to carry out this public education campaign. FDA intends to purchase advertising space from retailers on a voluntary basis and will not require that retailers participate in the campaign. Therefore, the comment raises an issue that is outside the scope of this proposed information collection.

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
Households (adults 18 and up)	Mail screener	9,217	1	9,217	0.17 (10 minutes)	1,567
	Field screener	8,753	1	8,753	0.17 (10 minutes)	1,488
	Telephone verification, field screener	733	1	733	0.08 (5 minutes)	59
Adult smokers, ages 25 to 54	Wave 1 questionnaire	1,427	1	1,427	0.67 (40 minutes)	956
	Wave 2–4 questionnaires	2,938	1	2,938	0.67 (40 minutes)	1,968
	Telephone verification, questionnaires 1–4	436	1	436	0.08 (5 minutes)	35
Study participants (opt in)	App-based questionnaire	769	3	2,308	0.08 (5 minutes)	185
Total						6,258

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

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23450 Filed 10–26–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

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 information collection provisions of the dispute resolution procedures for science-based decisions on products regulated by the Center for Veterinary Medicine (CVM).

DATES: Submit either electronic or written comments on the collection of information by December 26, 2017.

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 December 26, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 26, 2017. 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. FDA–2017–N–6145 for ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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