

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Glossary	689	1	689	4	2,756

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

Dated: September 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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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 October 11, 2013.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns". 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, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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-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 youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns will feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through 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 by minors, FDA requests OMB approval to collect information needed to evaluate FDA's general market youth tobacco prevention campaigns. 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 youth tobacco prevention campaigns: (1) An outcome evaluation study consisting of a youth experimenter and non-trier initiative and a male only youth rural

smokeless initiative and (2) a media tracking survey. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

- *Outcome Evaluation Study.* The outcome evaluation study consists of an initial baseline survey of youth aged 11 to 16 before the campaigns launch. The baseline will be followed by three longitudinal followup surveys of the same youth, aged 11 to 16, at approximate 8-month intervals after the campaigns launch. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18. Information will be 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 will measure tobacco use susceptibility and current use. Information will also be collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language. Finally, a baseline survey will also be conducted with the parent or legal guardian of each youth baseline survey participant in order to collect data on household characteristics and media use.

- *Media Tracking Survey.* The media tracking survey consists of assessments of youth aged 13 to 17 conducted at 4 months, 12 months, and 20 months post launch. The tracking survey will assess awareness of the campaigns 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 media advertising and variation in exposure to allow for mid-campaign refinements.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be 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 evaluation study and (2) an Internet

panel for the media tracking survey. Participation in the studies is voluntary.

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 survey will be 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. Data from the outcome evaluation study will be 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.

FDA's burden estimate is based on prior experience with in-person and Internet panel studies similar to the Agency's plan presented in this document. To obtain the target number of completed surveys ("completes") for the outcome evaluation study, 40,238 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response is 10 minutes (0.17), for a total of 6,840 hours. An estimated 8,057 youth will complete the Youth Baseline Questionnaire in order to yield 6,445 completes at the first followup; 5,156 completes at the second followup; and 4,125 completes at the third followup survey waves. The estimated burden per response is 30 minutes (0.5) for the baseline

questionnaire, for a total of 4,029 hours. The estimated burden per response is 45 minutes (0.75) for each followup questionnaire, for a total of 4,834 burden hours for the first Followup Questionnaire; 3,867 hours for the second Followup Questionnaire; and 3,094 hours for the third Followup Questionnaire. The parent or legal guardian of youth recruited to complete the Youth Baseline Questionnaire will also complete a Parent Baseline Questionnaire with an estimate burden per response of 10 minutes (0.17), for a total of 1,704 hours. Additionally for clarity, FDA has added male youth, aged 11–18, to the burden chart. This is not a new component to the information collection as they were already a component of the study that falls within the group of youth aged 11–18. The rural smokeless campaign component of the evaluation differs from the experimenter and non-trier campaigns component in one major way—only males in the age range will be considered eligible.

To obtain the target number of completes for the media tracking survey, 40,000 respondents will be contacted for each survey wave through an online invitation. The estimated burden per response is 2 minutes (0.03), for a total of 1,200 hours for the first Media Tracking Screener; 1,200 hours for the second Media Tracking Screener; and 1,200 hours for the third Media Tracking Screener. An estimated 4,000 youths will be recruited to complete each of the three waves of the media

tracking survey. The estimated burden per response is 30 minutes for each questionnaire, for a total of 2,000 hours for the first Media Tracking Questionnaire; 2,000 hours for the second Media Tracking Questionnaire; and 2,000 hours for the third Media Tracking Questionnaire.

The target number of completed campaign questionnaires for all responses is 211,859. The total estimated burden is 37,836 hours. After further review of the burden estimates, the Agency has revised the interview hourly burden in table 1, which was based on the number of samples needed to assess the campaigns in the final data collection request. The estimates are reflective of a decrease in the expected sample size and an increase in the timing for the screener followup surveys. The estimates of the sample size for the youth outcome baseline interviews in the 60-day **Federal Register** notice was an estimate for the general market population. The survey timing increased slightly for screeners and for followups because it was considered more realistic based on the instrument length.

In the **Federal Register** of June 21, 2013 (78 FR 37546), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, which were not PRA related, and are beyond the scope of this 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
Outcome Evaluation Study General Population/ Screener and Consent Process (Youth and Parent).	40,238	1	40,238	0.17 (10 minutes)	6,840
United States Youth aged 11 to 16/Youth Baseline Questionnaire (Experimenter and Non-Trier).	8,057	1	8,057	0.5 (30 minutes)	4,029
United States Youth aged 11 to 18/Youth First Followup Questionnaire (Experimenter and Non-Trier).	6,445	1	6,445	0.75 (45 minutes)	4,834
United States Youth aged 11 to 18/Youth Second Followup Questionnaire (Experimenter and Non-Trier).	5,156	1	5,156	0.75 (45 minutes)	3,867
United States Youth aged 11 to 18/Youth Third Followup Questionnaire (Experimenter and Non-Trier).	4,125	1	4,125	0.75 (45 minutes)	3,094
United States Rural Markets Male Youth aged 11 to 18/Youth Baseline Questionnaire.	1,969	1	1,969	0.50 (30 minutes)	985
United States Rural Markets Male Youth aged 11 to 18/Youth First Followup Questionnaire.	1,575	1	1,575	0.75 (45 minutes)	1,182
United States Rural Markets Male Youth aged 11 to 18/Youth Second Followup Questionnaire.	1,260	1	1,260	0.75 (45 minutes)	945
United States Rural Markets Male Youth aged 11 to 18/Youth Third Followup Questionnaire.	1,008	1	1,008	0.75 (45 minutes)	756

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Parent of Youth Baseline Survey Participants/ Parent Baseline Questionnaire.	10,026	1	10,026	0.17 (10 minutes)	1,704
United States Youth aged 13 to 17/First Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/First Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
United States Youth aged 13 to 17/Second Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/Second Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
United States Youth aged 13 to 17/Third Media Tracking Screener.	40,000	1	40,000	0.03 (2 minutes)	1,200
United States Youth aged 13 to 17/Third Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 minutes)	2,000
Total Hours	37,836

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

Dated: September 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0928]

Draft Guidance for Industry on Recommendations for Preparation and Submission of Animal Food Additive Petitions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #221) entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions.”

This draft guidance describes the types of information that FDA’s Center for Veterinary Medicine (CVM) recommends for inclusion in food additive petitions (FAPs) submitted for food additives intended for use in food for animals. It is intended to help the petitioner submit such FAP information in a consistent and appropriate manner.

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 on 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 November 12, 2013.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6864, sharon.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #221) entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions.” It is intended to help petitioners submit FAP information in a consistent and appropriate manner.

The requirements for submitting an animal food additive petition to FDA are set forth in section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) and 21 CFR part 571. This draft guidance provides information for complying with these requirements.

This draft guidance includes the following information:

- How to determine if an animal food ingredient is already the subject of an approved FAP.
- Who to contact for more information about approved food additives.
- Who to contact for more information on how to submit an FAP for approval.
- When and how to request a pre-petition consultation with CVM before submitting an FAP.
- When and how to submit study designs for CVM review.
- What data CVM considers adequate to support an FAP.
- Where to find other FDA guidances that may be helpful when preparing and submitting an FAP to CVM.
- General recommendations for the format of an FAP submission.
- Where and how to submit an FAP.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. 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