this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 26, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1696 Appointment of Representative

CMS–10536 Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Appointment of Representative; *Use:* The Appointment of Representative form is completed by beneficiaries, providers and suppliers, and any party seeking to appoint a representative to assist them with their initial determinations and filing appeals. *Form Number:* CMS–1696 (OMB control number: 0938–0950); *Frequency:* Once; *Affected Public:* Individuals and Households, and the Private sector (Business or other for-profits); *Number of Respondents:* 3,472,840; *Total Annual Responses:* 347,284; *Total Annual Hours:* 86,821. (For policy questions regarding this collection contact Katherine Hosna at 410–786–4993.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use:* To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, we will review the submitted information and documentation to make an approval determination for the advanced planning document. *Form Number:* CMS–10536 (OMB control number: 0938–1268); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 2,688. (For policy questions regarding this collection contact Martin Rice at 410–786–2417.)

Dated: December 20, 2017.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–27787 Filed 12–22–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign

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 an extension of the time period for the outcome evaluation of FDA's multicultural youth tobacco public education campaign, the addition of two rounds of data collection with the original youth surveyed for the outcome evaluation, and recruitment of new youth to participate in those two additional surveys.

DATES: Submit either electronic or written comments on the collection of information by February 26, 2018.

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 February 26, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 26, 2018. 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–2014–N–2294 for ''Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign'' 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 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign (OMB Control Number 0910–0788—Extension)

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 a youth-targeted public education campaign ('Fresh Empire') to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaign features events, advertisements on television and radio and in print, digital communications including social media, and 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 multicultural public education campaign will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences specific cognitive outcomes related to tobacco use that are targeted by the campaign.

FDA is in the process of evaluating the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that follows the multiple, discrete waves of media advertising planned for the campaign. All information collected is integral to that evaluation.

FDA's *Fresh Empire* youth tobacco public education campaign aims to reduce tobacco use among youth who affiliate with a hip-hop peer crowd, predominantly among African American, Hispanic, and Asian/Pacific Islander youth. The outcome evaluation of the campaign consists of a pre-test survey of youth aged 12 to 17 before campaign launch followed by a series of post-test surveys beginning approximately 6 months after the campaign launch. The post-test surveys are conducted among youth who participated in one or more surveys (the embedded longitudinal cohort) and new participants who are recruited to make up for attrition. Eligible youth were initially 12- to 17-year-old youth who are influenced by the hip-hop peer crowd. Youth in the embedded longitudinal cohort may reach the age of 18 over the course of the evaluation.

To date, the pre-test and two post-test surveys have been conducted. A third post-test survey is currently underway. Information has been collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information has also been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information is being collected through in-person and web-based questionnaires. Youth respondents were recruited from two sources: (1) A sample drawn from 30 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation, and (2) targeted social media (*e.g.,* Facebook).

This study is being conducted in support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to educate the population about the risks and potential risks of tobacco use. The information being collected is necessary to inform FDA's efforts towards these goals and to measure the effectiveness and public health impact of the campaign. Data from the outcome evaluation are being used to estimate awareness of and exposure to the campaign among youth in target markets where the campaign is active. Data are also being used to examine statistical associations between exposure to the campaign and subsequent changes in specific outcomes of interest, which include knowledge, attitudes, and beliefs related to tobacco use.

FDA requests OMB approval to extend OMB approval of the evaluation of FDA's multicultural youth tobacco public education campaign and to add two additional waves of data collection with existing youth in the study. To accommodate these two additional surveys, FDA requests approval to increase the number of burden hours under the existing control number. The fourth post-test survey will begin in July 2018. The fifth post-test survey will begin in February 2019. As was done in earlier post-test surveys, new youth will be recruited to participate to make up for attrition.

A total of 2,100 youth will complete questionnaires for the fourth post-test survey, and the same number will complete questionnaires for the fifth post-test survey. These respondents will include existing youth who have participated in one or more surveys previously (''Longitudinal Cohort'') and new youth recruited via a mail-based screener or social media ads (''Cross-Sectional Refresher Sample''). Based on earlier response rates and longitudinal respondents aging out of the eligibility criteria (over the age of 18), we expect to need to recruit a larger number of cross-sectional respondents than in previous waves. We estimate that approximately 600 longitudinal youth and 1,500 cross-sectional youth will participate in each of the fourth and fifth post-test surveys. With an estimated burden of 45 minutes per respondent, this adds 450 hours for longitudinal respondents and 1,125 hours for cross-sectional respondents for each of the fourth and fifth post-test evaluation surveys.

A mail-based screener was one of the methods used to identify eligible youth for the pre-test survey. This method will be used during the fourth post-test survey to recruit new youth to ensure that the sample composition is similar across rounds of data collection. As was done during the pre-test survey, parents or guardians will be asked to provide consent and their contact information on this form. For the fourth post-test survey, the 5-minute youth screener and the 1-minute parental consent will be completed by 9,869 households for a total of 822 burden hours for youth and an additional 164 hours for the parents or guardians. This method will not be used during the fifth post-test survey, for which new participants will be recruited only via social media.

We will continue to recruit new youth through social media (*e.g.,* Facebook, Instagram) as a secondary strategy to recruit youth 13 to 17. An online version of the screener described above will continue to be used to identify eligible youth. The screener will take 5 minutes and will be completed by an additional 4,000 youth during each of the fourth and fifth post-test surveys, for a total of 8,000 additional youth respondents and 666 total additional burden hours. The new total number of participants for the youth online post-test screener will be 32,000 and the total burden will be 2,666 hours. This includes the originally-approved 24,000 participants and 2,000 burden hours.

As was done previously, eligible youth aged 13 to 14 who complete the online screener will be asked to provide their parents' or guardians' contact information to provide parental consent for the main survey. The process of parents and guardians providing consent for eligible youth will take approximately 1 minute. For the fourth and fifth post-test surveys, we estimate that an additional 700 adults will be contacted to provide consent for eligible youth for a total of 11 additional burden hours. Added to the original 6,000 parents and 100 burden hours, the total number of parental online screener and consents will be 6,700 and the total burden will be 111 hours.

With these additions, the estimated number of respondents/responses for all waves of data collection for the study is 107,743, and the total burden is estimated at 15,135 hours—an increase of 4,813 hours from the last approval.

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
Youth aged 12 to 17 in the United States.	Mail Screener and Consent Process—Pre-test outcome survey.	13,816	1	13,816	0.0833	1,151
	Mail Screener and Consent Process—Post-test outcome survey.	9,869	1	9,869	0.0833	822
Adults 18 and older in the United States.	Mail Screener and Consent Process—Pre-test outcome survey.	13,816	1	13,816	0.0166	229
	Online Screener and Consent Process—Pre-test outcome survey.	520	1	520	0.0166	9
	Mail Screener and Consent Process—Post-test outcome survey.	9,869	1	9,869	0.0166	164
	Online Screener and Consent Process—Post-test outcome survey.	6,700	1	6,700	0.0166	111
Multicultural Youth aged 12 to 17 in select media markets.	Pre-test outcome evaluation survey.	2,194	1	2,194	0.5	1,097
Longitudinal Cohort, age 13 to 18 years.	First post-test evaluation survey.	1,722	1	1,722	0.75	1,292
	Second post-test evaluation survey.	1,752	1	1,752	0.75	1,314
	Third post-test evaluation survey.	1,365	1	1,365	0.75	1,024
	Fourth post-test evaluation survey.	600	1	600	0.75	450
	Fifth post-test evaluation survey.	600	1	600	0.75	450
Cross-Sectional Refresher Sample, age 13 to 17 years.	First post-test evaluation survey.	682	1	682	0.75	512
	Second post-test evaluation survey.	503	1	503	0.75	377
	Third post-test evaluation survey.	735	1	735	0.75	551
	Fourth post-test evaluation survey.	1,500	1	1,500	0.75	1,125
	Fifth post-test evaluation survey.	1,500	1	1,500	0.75	1,125
Multicultural youth aged 13 to 17 in the select media markets recruiting through social media and online panels.	Pre-test online screener	8,000	1	8,000	0.0833	666
	Post-test online screener ...	32,000	1	32,000	0.0833	2,666
Total	.....	107,743	.....	.....	.....	15,135

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

Dated: December 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27712 Filed 12–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2582]

Determination of Regulatory Review Period for Purposes of Patent Extension; STRIVERDI RESPIMAT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for STRIVERDI RESPIMAT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 26, 2018.