DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0306]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Administrative Detention and Banned Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Administrative Detention and Banned Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On February 8, 2013, the Agency submitted a proposed collection of information entitled ''Administrative Detention and Banned Medical Devices'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0114. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14810 Filed 6–20–13; 8:45 am]

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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) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed 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 August 20, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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 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 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 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 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 18 conducted at 4 months, 12 months, and 20 months postlaunch. 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, 55,695 youth respondents and their parent or legal guardian will be contacted through a screening and consent process. The estimated burden per response is 5 minutes (0.083), for a total of 4,623 hours. An estimated 12,940 youth will complete the Youth Baseline Questionnaire in order to yield 10,352 completes at the first followup, 8,281 completes at the second followup, and 6,625 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 6,470 hours. The estimated burden per response is 30 minutes (0.5) for each followup questionnaire, for a total of 5,176 burden hours for the first Followup Questionnaire, 4,141 hours for the second Followup Questionnaire, and 3,313 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 2,200 hours.

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 youth 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 respondents is 238,833. The total estimated burden is 35,523 hours. OMB approval is requested for 3 years.

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).	55,695	1	55,695	0.083 (5 min.) ...	4,623
Youth aged 11–18 in the United States.	Outcome Evaluation Youth Baseline Questionnaire.	12,940	1	12,940	0.5 (30 min.)	6,470
	Outcome Evaluation Youth 1st Followup Questionnaire.	10,352	1	10,352	0.5 (30 min.)	5,176
	Outcome Evaluation Youth 2nd Followup Questionnaire.	8,281	1	8,281	0.5 (30 min.)	4,141
	Outcome Evaluation Youth 3rd Followup Questionnaire.	6,625	1	6,625	0.5 (30 min.)	3,313

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
Parent of Youth Baseline Survey Participants.	Outcome Evaluation Parent Baseline Questionnaire.	12,940	1	12,940	0.17 (10 min.) ...	2,200
Youth aged 13–18 in the United States.	Screener	40,000	1	40,000	0.03 (2 min.)	1,200
	1st Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
	Screener	40,000	.....	40,000	0.03 (2 min.)	1,200
	2nd Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
	Screener	40,000	1	40,000	0.03 (2 min.)	1,200
	3rd Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
Total	.....	238,833	.....	.....	.....	35,523

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

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14809 Filed 6–20–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 in the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by August 20, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@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.

Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products—(OMB Control Number 0910–0675)—Extension

The guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet