

**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 Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.*

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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 Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleston@fda.hhs.gov](mailto:daniel.gittleston@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