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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14–0879]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Surveys of State, Tribal, Local, and Territorial (STLT) Governmental Agencies (OMB Control No. 0920–0879, Exp. 3/31/2013)—Revision—Office of the Director, Office for State, Tribal Local and Territorial Support (OSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's mission is to create the expertise, information, and tools that people and communities need to protect their health—through health promotion, prevention of disease, injury and disability, and preparedness for new health threats. CDC seeks to accomplish its mission by collaborating with partners throughout the nation and the world to: Monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training.

CDC is requesting a three-year approval for a generic clearance to collect information related to domestic public health issues and services that affect and/or involve state, tribal, local and territorial (STLT) government entities. The respondent universe is comprised of STLT governmental staff or delegates acting on behalf of a STLT agency involved in the provision of essential public health services in the United States. Delegate is defined as a governmental or non-governmental agent (agency, function, office or individual) acting for a principal or submitted by another to represent or act on their behalf. The STLT agency is represented by a STLT entity or delegate with a task to protect and/or improve the public's health. Information will be used to assess situational awareness of current public health emergencies; make decisions that affect planning, response and recovery activities of subsequent emergencies; fill CDC gaps in knowledge of programs and/or STLT governments that will strengthen surveillance, epidemiology, and laboratory science; improve CDC's support and technical assistance to states and communities. CDC will conduct brief data collections, across a range of public health topics related to essential public health services.

CDC estimates up to 30 data collections with STLT governmental staff or delegates, and 10 data collections with local/county/city governmental staff or delegates will be conducted on an annual basis. Ninety-five percent of these data collections will be web-based and five percent telephone, in-person, and focus groups. The total annualized burden of 54,000 hours is based on the following estimates.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of surveys per respondent type	Average burden per respondent (in hours)	Total burden hours (annual)
State, Territorial, or Tribal government staff or delegate.	Web, telephone, in-person, focus group.	800	30	1	24,000
Local/County/City government staff or delegate.	Web, telephone, in-person, focus group.	3,000	10	1	30,000
Total					54,000

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Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1151]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Direct-to-Consumer Promotion Directed at Adolescents

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, ''Experimental Study of Direct-to-Consumer (DTC) Promotion Directed at Adolescents.'' This study is designed to examine how adolescents interpret DTC advertising directed at them.

DATES: Submit written or electronic comments on the collection of information by December 30, 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: FDA PRA Staff, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 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.

Experimental Study of Direct-to-Consumer (DTC) Promotion Directed at Adolescents—(0910—NEW)

Regulatory Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Adolescents and DTC

Sponsors for several prescription drug classes market their products directly to vulnerable groups, including adolescents. Such DTC marketing to adolescents raises a variety of potential concerns. Adolescents are a unique audience for DTC drug marketing because their cognitive abilities are different than those of adults, and they are usually dependent on adults for health insurance coverage, health care provider access, and prescription drug payment. Despite this uniqueness, research regarding how adolescents use risk and benefit information for health-related decisions is limited. If considered at all in healthcare communication research, age is typically treated as simply another segment of the audience (Ref. 1), and researchers fail to consider how *information processing* (how people understand information) in response to ad exposure might differ among adolescents versus older viewers.

The FD&C Act requires manufacturers, packers, and distributors that advertise prescription drugs to disclose certain information about a product's uses and risks to potential consumers in all advertisements. Consumers must consider tradeoffs with regard to the product's risks and benefits in deciding whether to ask their health care professionals about the product. Presenting technically factual information is important, but other factors can also affect potential consumers. Information processing capacity, the relevance and vividness of the information, and contextual factors such as family dynamics likely affect how adolescent consumers weigh the potential risks and benefits of using a product.

Despite the lack of previous research specific to DTC drug marketing to adolescents, existing theoretical and empirical data make a strong case for treating adolescence as a unique life stage during which vulnerabilities that can affect informed decision-making must be taken into account. Well-known theories of adolescent development have long pointed to developmental changes that occur during the transitional period as an individual moves from childhood to young adulthood (Ref. 2). For instance, Erikson (Refs. 3, 4) describes an often turbulent psychosocial crisis that occurs as adolescents strive to develop their unique identify. Piaget (Refs. 5, 6) and Kohlberg (Ref. 7) describe changes in stages relative to cognitive processing and reasoning that occur in this period, as the adolescent becomes increasingly capable of more abstract thinking. Different cognitive, social and emotional, and developmental processes in the adolescent brain mature simultaneously and at different rates, affecting decision-making by age. All of these factors can influence how adolescents perceive and process information as well as weigh risks and benefits.

The need for understanding how adolescents weigh risks and benefits is particularly critical given the potential