

is unavailable, you may contact Mr. Jeffrey J. Gee, Acting Chief, Investigations and Hearings Division, by telephone at (202) 418-1420 and by email at [Jeffrey.Gee@fcc.gov](mailto:Jeffrey.Gee@fcc.gov).

Federal Communications Commission.

**Jeffrey J. Gee,**

*Acting Chief, Investigations and Hearings Division, Enforcement Bureau.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-15-14A00]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through

the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Monitoring and Reporting System for the Division of Community Health's Cooperative Agreement Programs—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

In September 2014, the Division of Community Health (DCH), Centers for Disease Control and Prevention (CDC), announced 93 awards under three new cooperative agreement programs authorized by the Public Health Service Act and the Prevention and Public Health Fund of the Affordable Care Act (FOA DP14-1417, FOA DP14-1418, and FOA DP14-1419PPHF14). The new programs are designed to address chronic diseases and risk factors for chronic diseases, including physical inactivity, poor diet, obesity, and tobacco use. The programs will provide support for implementation of broad, evidence- and practice-based policy and environmental improvements in a mix of 93 large and small cities, urban rural areas, tribes, multi-sectorial community coalitions, and racial and ethnic communities experiencing chronic disease disparities. Awardees include a

combination of 41 state, local, and tribal governmental agencies and 52 non-governmental (private sector) entities.

CDC is seeking OMB approval to collect information from the new DCH awardees utilizing an electronic Policy, Environment, Programmatic, and Infrastructure Database (PEPID) designed to enable the accurate, reliable, uniform and timely submission to CDC of each awardee's work plan and progress reports. Monitoring allows CDC to determine whether an awardee is meeting performance goals, to make adjustments in the type and level of technical assistance provided to them, and to provide oversight of the use of federal funds. The burden per response for routine, semi-annual reporting through PEPID is three hours. The burden estimate also includes a one-time allocation of 15 hours for initial population of the PEPID system, which is annualized over the period of the information collection request.

CDC is also requesting OMB approval to conduct targeted, special purpose information collections on an as-needed basis. Due to substantial interest in the new cooperative agreement programs, CDC estimates that each DCH awardee could be asked to participate in one special purpose information collection per year to supplement routine progress reporting. Each special purpose information collection request will be submitted to OMB for approval through the Change Request mechanism, and will include the data collection instrument(s) and a description of purpose and methods. The ability to conduct special purpose data collections will enable CDC to effectively manage programmatic activities and respond to inquiries. The estimated burden per response for each special data request is six hours.

OMB approval is requested for three years. Participation is required for cooperative agreement awardees. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,596.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
DCH Program Awardees (state, local and tribal government entities).	DCH PEPID: Initial population .....	14	1	15
	DCH PEPID: Semi-annual reporting	41	2	3
	Special PEPID Request .....	41	1	6
DCH Program Awardees (private sector entities) .....	DCH PEPID: Initial population .....	18	1	15
	DCH PEPID: Semi-annual reporting	52	2	3
	Special Data Request .....	52	1	6

**Leroy A. Richardson,**  
*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-2014-N-0168]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Disclosure Regarding Additional Risks in Direct- to-Consumer Prescription Drug Television Advertisements

**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:** Submit either electronic or written comments on the collection of information by February 12, 2015.

**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](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "Disclosure Regarding Additional Risks in Direct-to-Consumer (DTC) Prescription Drug Television (TV) Advertisements (Ads)." 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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.

#### Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television

##### Advertisements—(OMB Control Number 0910-NEW)

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(b)(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.

Prescription drug advertising regulations (21 CFR 202.1) require that broadcast (TV or radio) advertisements present the product's major risks in either audio or audio and visual parts of the advertisement; this is often called the "major statement." There is concern that as currently implemented in DTC ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic non-compliance due to fear of side effects. At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information. These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are serious and actionable, and include a disclosure to alert consumers that there are other product risks not included in the ad. For example, the disclosure could be, "This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for more information." The Office of Prescription Drug Promotion plans to investigate the effectiveness of this "limited risks plus disclosure" strategy through empirical research.

Our primary hypothesis is that, relative to inclusion of the full major statement, providing limited risk information along with the disclosure about additional risks will promote improved consumer perception and understanding of serious and actionable drug risks. We will also investigate other questions such as whether overall drug risk and benefit perceptions are

affected by these changes. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described further in this document, we will have sufficient power to detect small-to-medium sized effects in the main study.

Participants will be consumers who self-identify as having been diagnosed with one of three possible medical conditions: Depression, high cholesterol, or insomnia. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take approximately 30 minutes.

Within medical condition, participants will be randomly assigned to view one of four possible versions of a DTC ad, as depicted in table 1. One version will present the full major statement without the disclosure regarding additional risks (Conditions C, G, and K). This version will implement existing ads in the marketplace. Stimuli variations for the other three versions will be achieved by replacing the audio track of the original ad with the revised risk and disclosure statements described previously. Thus, a second version of the ad will include the full major statement plus the disclosure about additional risks (Conditions A, E, and I). A third version will include an abbreviated statement of risks without the disclosure about additional risks (Conditions D, H, and L). The fourth version will include an abbreviated statement of risks as well as the disclosure about additional risks (Conditions B, F, and J).

After viewing the ad, participants will respond to questions about information in the ad. Measures are designed to assess perception and understanding of product risks and benefits; perception and understanding of the disclosure about additional risks; perceptions of product quality; intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. The questionnaire is available upon request.