

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.*

[FR Doc. 2015-00355 Filed 1-12-15; 8:45 am]

**BILLING CODE 6712-01-P**

**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.