

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-0920]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers (Generic ICR, OMB# 0920-0920, Expires 2/28/2015)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In response to the continued HIV epidemic in our country, CDC has launched Act Against AIDS, a 5-year, multifaceted communication campaign to reduce HIV incidence in the United States. CDC plans to release the campaign in phases, with some of the phases running concurrently. Each phase of the campaign will use mass media and direct-to-consumer channels to deliver HIV prevention and testing messages. Some components of the campaign will be designed to provide basic education and increase awareness of HIV/AIDS among the general public, and others will be targeted to specific

subgroups or communities at greatest risk of infection. The current study addresses the need to assess the effectiveness of these social marketing messages aimed at increasing HIV awareness and delivering HIV prevention and testing messages among at-risk populations.

This extension of an ongoing study will evaluate the *Act Against AIDS* (AAA) social marketing campaign aimed at increasing HIV/AIDS awareness, increasing prevention behaviors, and improving HIV testing rates among consumers. A total of 12,000 respondents were originally approved for this generic ICR (0920-0920) and since the original approval date, 1,250 respondents have participated in the surveys under the following mini ICRs: 0920-13AHP; 0920-13YR and 0920-13DD. The information collected from each of the data collections were used to evaluate specific AAA campaign phases. We are requesting additional time to continue to survey other AAA target audiences and campaign phases and measuring exposure to each phase of the campaign and interventions implemented under AAA. Through this extension, we plan to reach the remaining approved 10,750 respondents. In order to obtain the remaining respondents, we anticipate screening approximately 17,915 individuals.

Depending on the target audience for the campaign phase, the study screener will vary. The study screener may address one or more of the following items: race/ethnicity, sexual behavior, and sexual orientation. Each survey will have a core set of items asked in all rounds, as well as a module of questions relating to specific AAA activities and communication initiatives.

Survey respondents will be selected from a combination of sources, including a national opt-in email list sample and respondent lists generated by partnership organizations (e.g., the National Urban League, the National Medical Association). A total of 10,750 participants will self-administer the survey at home on personal computers over a 3-year period.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals (male and female) aged 18 years and older.	Study Screener	17,915	1	2/60	597

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals (male and female) aged 18 years and older.	Survey Module	3,583	1	30/60	1,792
Total	2,389

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-0373]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Risk and Benefit Perception Scale Development

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: Fax written comments on the collection of information by December 22, 2014.

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. All comments should be identified with the

OMB control number 0910-New and title, “Risk and Benefit Perception Scale Development.” 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, PRASStaff@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.

Risk and Benefit Perception Scale Development (OMB Control Number 0910-New)

Section 1701(a)(4) of the Public Health Service Act (PHS 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.

FDA requires that prescription drug advertisements be balanced in their presentation of risk and benefit information. Patients receive information on drugs not only from their doctors and pharmacies, through patient labeling and FDA-mandated Medication Guides, but also online, on social networks and via direct-to-consumer (DTC) television and print advertising. Moreover, research suggests that consumers struggle with the concepts of risk and efficacy (Ref. 1) and often overestimate drug efficacy (Ref. 2).

As a result, it is important for FDA to understand and accurately measure how consumers are making sense of this information and how it impacts decisions related to prescription drugs.

FDA’s Office of Prescription Drug Promotion (OPDP) has an active research program that investigates how DTC advertising influences consumer knowledge, perceptions, and behavior. As OPDP’s research program has matured, the way in which we measure risk and benefit perception has evolved over time. This has resulted in perception measures that, while internally valid, tend to vary by study. Consequently, FDA needs a pool of reliable and valid measurement items for assessing consumers’ drug risk and benefit perceptions—as well as other elements of prescription drug decision making—consistently across studies. The purpose of this project is to create that measurement pool, thus increasing the rigor and efficiency of FDA’s research.

I. Design Overview

We will conduct pretesting prior to main data collection to assess the psychometric properties and identify any measurement challenges (e.g., misinterpretation, lack of variance) with candidate measurement items. We also will use the pretesting to examine factors that may affect future study results and analyses (e.g., response scale midpoints, moderating variables). We will conduct two sequential pretest waves (n=500 per wave; n=1,000 total) with the following target populations: (1) Individuals diagnosed with chronic pain and (2) individuals diagnosed with hypertension.

EXHIBIT 1—PRETEST STUDY DESIGN

Wave	Medical condition		
	Chronic pain	Hypertension	
Wave 1	n=250	n=250	500
Wave 2	n=250	n=250	500
Total	500	500	1,000