community-based programs that employ multiple policy and environmental change strategies.

Information to be collected from participating CTG awardees includes the interventions to be implemented; expenditures for labor, personnel, consultants, materials, travel, services, and administration; in-kind contributions; and partner organizations and their expenditures. Information will be collected electronically via a user-friendly, Web-based CTG Cost Study Instrument (CTG–CSI). Respondents will be a subset of 30 out of 35 CTG awardees funded specifically for implementation activities. CDC will select awardees for participation in the cost data collection based on a list of priority interventions appropriate for cost analysis.

Results of this data collection and planned analyses, including improvements in CDC's analytic and modeling tools, will be used to assist CTG awardees, CDC, and HHS in choosing intervention approaches for particular populations that are both beneficial to public health and cost-effective.

OMB approval is requested for the first three years of a five-year project with first data collection beginning approximately July 2012. CDC plans to seek an extension of OMB approval to support information collection through the end of the five-year award period.

Information will be collected electronically on a quarterly schedule. The estimated burden per response is 11 hours and there are no costs to respondents except their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
CTG Awardee	CTG–CSI	30	4	11	1,320

Dated: December 2, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–31622 Filed 12–8–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Low Income Home Energy Assistance Program LIHEAP Leveraging Report.

OMB No.: 0970–0121.

Description: The LIHEAP leveraging incentive program rewards LIHEAP grantees that have leveraged non-federal home energy resources for low-income households. The LIHEAP leveraging report is the application for leveraging incentive funds that these LIHEAP grantees submit to the Department of Health and Human Services for each fiscal year in which they leverage countable resources. Participation in the leveraging incentive program is voluntary and is described at 45 CFR 96.87. The LIHEAP leveraging report obtains information on the resources leveraged by LIHEAP grantees each fiscal year (as cash, discounts, waivers, and in-kind); the benefits provided to low-income households by these resources (for example, as fuel and payments for fuel, as home heating and cooling equipment, and as weatherization materials and installation); and the fair market value of these resources and benefits.

HHS needs this information in order to carry out statutory requirements for administering the LIHEAP leveraging incentive program, to determine countability and valuation of grantees leveraged non-federal home energy resources, and to determine grantees shares of leveraging incentive funds. HHS proposes to request a three-year extension of OMB approval for the currently approved LIHEAP leveraging report information collection.

Respondents: State, Local or Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Leveraging Report	70	1	38	2,660

Estimated Total Annual Burden Hours: 2,660.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *Email address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden information to be collected; and (e) 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. Consideration will be given

to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–31572 Filed 12–8–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0457]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Comparative Direct-to-Consumer Advertising

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 January 9, 2012.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title, ''Experimental Study of Comparative Direct-to-Consumer Advertising.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7651, *juanmanuel.vilela@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.

Experimental Study of Comparative Direct-to-Consumer Advertising—(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 903(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.

Regulations specify that sponsors cannot make comparative efficacy claims in advertising for prescription drugs without substantial evidence, most often in the form of well-controlled clinical trials, to support such claims (21 CFR 202.1(e)(6)(ii); 21 CFR 314.126). FDA has permitted some comparisons based on labeled attributes, such as indication, dosing, and mechanism of action. When substantial evidence does not yet exist, sponsors have used communication techniques that invite implicit comparisons, such as making indirect comparisons, using comparative visuals, and using vaguer language. This study is designed to apply the existing comparative advertising literature to direct-to-consumer (DTC) advertising, where little research has been conducted to date.

Moreover, as part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), the Agency for Healthcare Research and Quality is in the process of securing a large compendium of information on the comparative effectiveness of medical treatments in 14 priority medical conditions, including arthritis, cancer, dementia, depression, diabetes, and substance abuse (Ref. 1). As part of this process, they will fund a set of CHOICE (Clinical and Health Outcomes Initiative in Comparative Effectiveness) studies designed to explore comparative effectiveness. When this large project is completed, FDA will have additional information to consider when regulating DTC advertising. It is possible that more DTC advertising will be comparative in nature. In preparation for this change, FDA is embarking on the proposed research to ensure that it has adequate information to assess whether comparative DTC ads provide truthful and nonmisleading information to consumers.

A. Comparative Advertising

Comparative advertisements typically compare two or more named or recognizably presented brands of the same product category, although some comparative advertisements implicitly compare a product to other brands by making superiority statements (e.g., ''Only Brand A can be cooked in five minutes or less.''). These ads are frequently used for commercial products, such as electronics, food products, and automobiles.

Marketing and advertising studies have investigated the influence of comparative ads, particularly in contrast to noncomparative ads (Refs. 2 to 5). Research specifically investigating the effects of comparative advertising on consumer attitudes—including attitudes toward the ad, the brand, and product use—has produced mixed results (Refs. 4 and 6). The research findings on the superiority of comparative versus noncomparative ads on purchase intentions, however, have been more conclusive. Relative to noncomparative ads, comparative ads were shown to result in greater purchase intentions (Refs. 2 to 4 and7). Finally, other evidence suggests that there may be more potential for consumers to confuse brands when viewing comparative versus noncomparative ads. Brands advertised in a comparative format were shown to be more likely to be perceived as similar to the leading brand than brands advertised in a noncomparative format (Refs. 8 to 10).

B. Comparative Prescription Drug Advertisements

Despite extensive research on comparative advertising of consumer products and a limited number of studies on how DTC ads could help consumers compare drugs (Refs. 11 and 12), very little research has been conducted on comparative prescription drug advertisements (Ref. 13). Consequently, it is unclear whether these findings are applicable to comparative drug ads or how such claims influence consumers' perceived efficacy of advertised drugs.

Currently, most DTC ad comparisons focus on drug attributes, such as differences in dosing or administration method (see 21 CFR 314.126). Because few head-to-head clinical trials have been conducted, very few DTC ads include efficacy-based comparisons (Ref. 13). The present study aims to investigate how consumers interpret and react to DTC comparative drug ads. Specifically, the study will explore two types of drug comparisons in DTC ads: (1) Drug efficacy comparisons and (2) other evidence-based comparisons, such as dosing, mechanism of action, and indication. The study findings will inform FDA of relevant consumer issues relating to comparative DTC advertising.

C. Design Overview

The proposed research will occur in two concurrent phases. The goal of Phase I is to: (1) Explore how consumers understand and interpret print and