resistance and quantify HIV subtypes among persons infected with HIV and to monitor and evaluate perinatal HIV prevention efforts. Health departments funded for these supplemental data collections obtain this information from laboratories, health care providers, and medical records. CDC estimates that 25 health departments will be reporting data elements containing HIV Incidence Surveillance (HIS) data, 53 health departments will report additional data elements on HIV nucleotide sequences as part of MHS, and 35 areas will be reporting data as part of PHER annually. The total estimated annual burden hours are 53,700.

Estimated Annualized Burden Hours

EXHIBIT 12.A ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average Burden per response (in hours)
Health Departments	Adult HIV Case Report	59	1,260	20/60
Health Departments	Pediatric HIV Case Report	59	6	20/60
Health Departments	Case Report Evaluations	59	127	20/60
Health Departments	Case Report Updates	59	1,469	2/60
Health Departments	Laboratory Updates	59	5,876	1/60
Health Departments	HIV Incidence Surveillance (HIS)	25	2,729	10/60
Health Departments	Molecular HIV Surveillance (MHS)	53	967	5/60
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–31010 Filed 12–21–12; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 3:00 p.m.—4:10 p.m., EDT, January 23, 2013.

Place: Teleconference.

Status: Open to the public, limited only by the availability of telephone ports. The public is welcome to participate during the public comment period. A public comment period is tentatively scheduled from 4:00 p.m. to 4:05 p.m. To participate in the teleconference, please dial (877) 953–5019 and enter code 5280655.

Purpose: The subcommittee will provide advice to the CDC Director through the ACD on strategic and other broad issues facing CDC.

Matters To Be Discussed: Agenda items will include the following: review of draft recommendations for health equity at CDC.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, HDS, ACD, CDC, 1600 Clifton Road NE., M/S E–67, Atlanta, Georgia 30333, telephone (404) 498–2320, email: *LEL1@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 18, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–31008 Filed 12–21–12; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0176]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Examination of Corrective Direct-to-Consumer Television 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 25, 2013.

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: Examination of Corrective Direct-to-Consumer Television Advertising.'' Also include

the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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: Examination of Corrective Direct-to-Consumer Television Advertising—(OMB Control Number 0910—New)

Section 1701(a)(4) of the Public Health Service Act (42 CFR 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 CFR 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.

FDA regulations require prescription drug ads to contain accurate information about the benefits and risks of the drug advertised. When this is not the case, corrective advertising is designed to dissipate or correct erroneous beliefs resulting from a false claim (Refs. 1 and 2). Corrective advertising emerged in public debate in the United States in the 1970s as a hypothetical remedy for deceptive advertising, having first been proposed by Georgetown University law students in 1969 as a way of dispelling the effects of deceptive advertising (Ref. 3). Corrective advertising is one remedy FDA may request in response to false or misleading prescription drug promotion. In 2009, for example, Bayer HealthCare Pharmaceuticals produced and aired corrective DTC advertising for Yaz, a birth control pill, following a warning from FDA regarding misleading claims (Ref. 4). Despite these developments, researchers and policymakers currently lack empirical literature regarding the various influences of corrective DTC ads on prescription drug consumers. The current project will examine the influence of corrective messages in the realm of consumer directed prescription drug advertising.

Design Overview

Phase 1 will vary the exposure to the messages (*original ad alone* vs. *original + corrective* vs. *corrective ad* alone). The goal of Phase 1 is to examine how exposure to a combination of original and corrective DTC ads affects message recall, message comprehension, perceived drug efficacy, perceived drug risk, and intentions to ask about or use the drug. Specifically, we will compare consumers who see both the original and corrective ad with those who see only the original ad, only the corrective ad, and neither ad. Participants in the Control condition will see a reminder ad for the product to control for brand name exposure.

TABLE 1—DESIGN OF PHASE 1: ORIGINAL EXPOSURE BY CORRECTIVE EXPOSURE

Exposure to original ad	Exposure to corrective ad	
	Yes	No
Yes	.....	Control (Reminder ad)
No	.....	

Phase 2 will examine the similarity of the corrective ad's theme and visual elements to those of the original ad (*same ad elements* vs. *some similar ad elements* vs. *different ad elements*) and the exposure delay (time) between viewing the original ad and the corrective ad (*no delay* vs. *1 week delay* vs. *1 month delay* vs. *6 month delay*). The purpose of Phase 2 is to examine whether a corrective ad's ability to correct misinformation is related to: (1) Corrective ad similarity to the original ad and (2) time delay between original ad and corrective ad exposure.

We will systematically vary these two characteristics to create a study with a 4 (similarity to original ad) x 4 (exposure delay) design (see Table 2).

TABLE 2—DESIGN OF PHASE 2: CORRECTIVE AD SIMILARITY BY EXPOSURE TIME DELAY

Corrective ad similarity	Multiple exposure pod (2 viewings per sitting, for a total of 6 exposures*)	Time between Original and Corrective			
		None	1 Week	1 Month	6 Months
Same ad elements as original					
Some similar elements as original					
Different ad elements than original					
Control (Do not see corrective)*					

*The control condition will be used to examine the impact of time delay on perceptions and intentions.

Prior to conducting the main study, we will pretest the stimuli, questionnaires, and data collection process. The first set of pretests will focus on the stimuli to: (1) Ensure participants perceive the stimuli as realistic and (2) ensure participants notice and comprehend the original and corrective messages in the ads. The second pretest will focus on the questionnaires and data collection process. Its purpose will be to: (1) Ensure that survey questions solicit responses that meet the study's analytic goals and (2) ensure data are captured and stored accurately for each question. The pretests are not intended to affect the study design, sample or burden.

All parts of this study will be administered over the Internet. A total of 6,650 interviews will be completed. Participants will be randomly assigned to view one version of a DTC prescription drug television ad. Following their perusal of this ad, they will answer questions about their recall and understanding of the benefit and risk information, their perceptions of the benefits and risks of the drug, and their intent to ask a doctor about the medication.

Demographic and numeracy information will be collected. In addition, participants will answer questions about their familiarity with their medical condition. The entire procedure is expected to last approximately 25 minutes in Phase 1 and 1 hour in Phase 2. This will be a one-time (rather than annual) information collection.

Participants will be randomly assigned to view one version of a DTC prescription drug television ad. Following their perusal of this ad, they will answer questions about their recall and understanding of the benefit and risk information, their perceptions of the benefits and risks of the drug, and their intent to ask a doctor about the

medication. Demographic and numeracy information will be collected. In addition, participants will answer questions about their familiarity with their medical condition. The entire procedure is expected to last approximately 20 minutes. This will be a one-time (rather than annual) information collection.

In the **Federal Register** of February 29, 2012 (77 FR 12307), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three public submissions. In the following section, we outline the observations and suggestions raised in the comments and provide our responses.

(Comment 1) One comment expressed support for the survey.

(Response) We thank this commenter for his support of our study.

(Comment 2) One comment expressed the concern that the Internet sample would not measure individuals over 65 due to difficulties using the Internet.

(Response) We have conferred with the Internet Panel provider for this study about this issue. According to GfK,[1] the 65+ Panelists are among the most reliable respondents and their representation on the panel (15.7 percent) is reasonably proportionate to their representation in the General Population (16.7 percent).

(Comment 3) One comment stated a ''medium prevalence'' condition may not represent conditions that cluster in particular demographic groups.

(Response) Recruitment to KnowledgePanel® is based upon a random selection of residential addresses. Every residential address in the United States has an equal probability of selection within each recruitment cohort (cohort sizes may vary from recruitment wave to wave and the residential housing stock changes over time which results in differing probability of selection between recruitment waves). Thus, mailings have a proportional likelihood of reaching any specific demographic group. Finally, as the weights are calculated based upon Current Population Survey benchmarks, final adjustment of survey respondents to the U.S. population can be easily made. The panel recruits in English and Spanish with all mailings being bilingual.

We plan to use asthma and weight loss as our two medical conditions. While the particulars of an individual corrective campaign may vary, the type of violation (for example, overstatement of efficacy, minimization of risk) can occur in any drug class. Therefore, we believe that the cognitive processes involved in understanding a claim and subsequently addressing problematic claims applies across multiple medical conditions. Those with debilitating conditions might be less likely to respond to the recruitment and survey invitations but it is likely that they would be less likely to respond to other modes of survey data collection as well.

Finally, we note that this is a randomized control trial design: we are not attempting to make population estimates from these results.

(Comment 4) One comment asked if the participants would be a random and representative selection of the target audience.

(Response) We are planning to recruit panel members who self-report having been diagnosed with asthma (Phase 1) or self-identify as having a weight problem with a BMI of 25 or above (Phase 2). These are the relevant target audiences for the medical conditions being advertised. As described above, the panel of active profiled adults is weighted to be representative of the U.S. population on age, gender, race, Hispanic ethnicity, language proficiency, region, metro status, education, household income, home ownership, and Internet access using post-stratification adjustments to offset nonresponse or noncoverage bias.

(Comment 5) One comment stated that even if participants are randomly selected, the final study sample may be self-selected due to dropout over time.

(Response) We agree that dropout is a concern common to all longitudinal research. We plan to employ the following techniques to improve retention of respondents over time:

1. It is very important to notify respondents at the time of their invitation that this is a longitudinal survey and that we intend to contact them multiple times during the duration of the survey. This in an important part of the informed consent procedure. We will therefore explicitly ask respondents if we can contact them in the future. This will allow us to contact them even if they leave the panel.

2. Periodic contact also provides a vehicle to retain engagement with respondents and can be conducted via email. KnowledgePanel® members are accustomed to receiving periodic communication about surveys that they previously participated in and respond well to periodic contact.

3. When later survey waves are fielded, respondents will be reminded that they participated in the earlier survey wave, that we appreciated their agreeing to participate in subsequent survey waves and that this survey is a follow-on to the prior survey wave. The date of the prior survey field wave will be included.

4. Finally, even if a respondent has left the panel, respondents have given explicit permission, as was noted in item 1 above, to contact them regarding this survey. Thus we do not anticipate an unusual loss of participation on subsequent survey waves. In past multiwave surveys, it was not unusual for 75 percent to 85 percent of respondents to the first wave of a study to respond to a subsequent survey wave more than 1 year later.

(Comment 6) One comment questioned whether the study would be adequately powered to ensure meaningful results.

(Response) We have powered our study to detect small to medium effect sizes. We have provided a power analysis for both the main study phases and pretests.

(Comment 7) One comment suggested that rather than similarity and time delay, the proposed study should include an evaluation of both: (1) A truly informative, nondistracting, clear and conspicuous corrective ad and (2) an unclear and inconspicuous corrective ad.

(Response) We appreciate the suggestion to include clarity as an independent variable. Because we cannot study every variable of potential interest in a single study, we offer the following explanation for our choice of similarity and time delay. FDA has previously provided guidance on ways in which separate ads may be implemented in such a way as to be perceived as linked to one another:

> Psychology and marketing research suggests that the greater the perceptual similarity between disease awareness communications and reminder or product claim promotions (i.e., similarities in terms of their themes, such as story lines, or other presentation elements, such as colors, logos, tag lines, graphics, etc.), and the closer they are presented physically or in time to one another, the more likely it is that the separate messages contained in the two pieces will be remembered together in memory as one entity. Perceptual similarity is an important factor because research indicates that pieces are most likely to be linked together in memory when they have prominent cues in common, such as distinctive visual elements, a common narrator or background music, or a common story line. (Ref. 5.)

The recommendations in this guidance were based on the social science literature which suggests these properties influence people's associations. We selected similarity and time delay as our independent variables of interest in this study in order to

[1] Formerly Knowledge Networks.

provide information on the effectiveness of FDA guidance on this issue.

(Comment 8) Two comments expressed concern that the time delay conditions were not realistic, stating that a time delay of 6 months to a year might be more realistic.

(Response) We agree that a 6-month exposure delay more closely approximates real-world exposure to original and corrective messaging. In response to concerns about the realism of our approach, we have changed the study design in two ways (see Table 2). First, participants will view the stimuli embedded in a ''clutter reel'' of other ads three times over a 3-week period to approximate multiple exposures in a real-world context. Second, we have added a 6-month delay condition.

(Comment 9) One comment critiqued the references included in the 60-day **Federal Register** notice, stating:

''* * * the references offered in the instant [sic] notice seemed less concerned with presenting corrective advertising in a manner most likely to inform the consumer about the safety and efficacy of a given product and more concerned with determining whether the corrective ad might be bad for sales. Furthermore, the only example of application of a judicial remedy to enforce corrective advertising cited by one of these references distorted the clear intent of the opinion cited.''

(Response) Some of the research on corrective advertising, as the commentator notes, has assessed potential damage to an advertiser's reputation. Darke and colleagues (2008, Ref. 1) note the possibility of reputational damage, for example. Other papers cited in the 60-day notice, though, do not focus primarily on reputational damage. Mazis' work, both in the 1970s and 1980s and then again more recently (e.g., Mazis, 2001, Ref. 6), as we have seen a resurgence of corrective advertising, has been concerned with the efficacy of corrective messages. Mazis and colleagues (1983, Ref. 3), for example, focused attention on the extent to which viewers actually noticed and remembered the corrective message inserted into Listerine ads. Moreover, our study was designed to address a gap in the literature—there is scant work on the specific efficacy of televised corrective ads intended to address claims made regarding prescription drugs—rather than to simply extend and replicate past literature. The primary focus of our study is correction of misperceptions that arise from prescription drug advertising. The dependent variables we describe in the 60-day notice do not include advertiser reputation but rather are comprised of constructs such as belief in advertised claims that overstate efficacy or minimize risk, perceived risk of the advertised drug, and perceived efficacy of the advertised drug.

Please note that in response to all comments received, whether we have adopted the suggestions or not, we will specifically examine the items mentioned in cognitive testing. During this testing, nine respondents will participate in the survey while explaining why and how they have chosen their answers and which questions they find difficult to respond to or to understand.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden response	Total hours
Sample availability (pretests and main survey)	24,635				
Screener completes (60%)	14,891	1	14,891	0.0333	496
Eligible (85%)	12,658				
Pretest (stimuli) completes (65%)	1,450	1	1,450	0.333	483
Pretest (questionnaire) completes (65%)	200	1	200	0.5	100
Phase 1 completes (65%)	1,000	1	1,000	.416	417
Phase 2 completes (45%)	4,000	1	4,000	1	4,000
Pretest/Study completes	6,650				
Total					5,496

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the total annual estimated burden imposed by this collection of information as 5,496 hours for this one-time collection.

V. References

The following references have been placed on display at the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday (FDA has verified the Web site addresses of the following references, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

1. Darke, P. R., Ashworth, L., and Ritchie, R. J. B. (2008). Damage from corrective advertising: Causes and cures. *Journal of Marketing,* 72, 81–97;

2. Mazis, M. B. & Adkinson, J. E. (1976). An experimental evaluation of a proposed corrective advertising remedy. *Journal of Marketing Research,* 13, 178–183.

3. Mazis, M. B., McNeill, D. L., & Bernhardt, K. L. (1983). Day-after recall of Listerine corrective commercials. *Journal of Public Policy & Marketing,* 2, 29–37.

4. Singer, N. (2009, February 11). A birth control pill that promised too much. *The New York Times,* p. B1.

5. From Guidance for Industry: ''Help-Seeking'' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms. Available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf.* Last accessed November 23, 2012.

6. Mazis, M. B. (2001). *FTC* v. *Novartis:* The return of corrective advertising? *Journal of Public Policy & Marketing,* 20, 114–122.

Dated: *December 20, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31028 Filed 12–21–12; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0643]

Draft Guidance for Industry on Electronic Source Data in Clinical Investigations; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.