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

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

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.

[F: Doc. 2012–31008 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 23, 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., P500-400B, 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 0090—New)

Section 1701(a)(4) of the Public Health Service Act (42 CFR 300(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

<table>
<thead>
<tr>
<th>Exposure to original ad</th>
<th>Exposure to corrective ad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Control (Reminder ad)</td>
<td></td>
</tr>
</tbody>
</table>

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. 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

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

*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.
(Comment 2) One comment expressed the concern that the Internet sample would not measure individuals over 65 due to difficulties using the Internet. (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). Thus, mailings have a proportional likelihood of reaching any specific demographic group.

(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). 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.

(Comment 4) One comment asked if the participants would be a random and representative selection of the target audience.
(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.
(Comment 6) One comment questioned whether the study would be adequately powered to ensure meaningful results.
(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.
(Comment 8) One comment stated “nonresponse or noncoverage bias.”
(Comment 9) One comment expressed interest in a single study, we offer the suggestion to include clarity as an independent variable. Because we cannot test 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.), the closer they are remembered together in memory. Similar claims apply 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 10) One comment stated a “medium prevalence” condition may not represent conditions that cluster in particular demographic groups.

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). 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.

4 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 criticized the references included in the 60-day Federal Register notice, stating:

“This *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>
<thead>
<tr>
<th>Activity</th>
<th>No. of respondents</th>
<th>No. of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample availability (pretests and main survey)</td>
<td>24,635</td>
<td></td>
<td></td>
<td></td>
<td>496</td>
</tr>
<tr>
<td>Screener completes (60%)</td>
<td>14,891</td>
<td>1</td>
<td>14,891</td>
<td>0.0333</td>
<td></td>
</tr>
<tr>
<td>Eligible (85%)</td>
<td>12,658</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pretest (stimuli) completes (65%)</td>
<td>1,450</td>
<td>1</td>
<td>1,450</td>
<td>0.333</td>
<td>483</td>
</tr>
<tr>
<td>Pretest (questionnaire) completes (65%)</td>
<td>200</td>
<td>1</td>
<td>200</td>
<td>0.5</td>
<td>100</td>
</tr>
<tr>
<td>Phase 1 completes (65%)</td>
<td>1,000</td>
<td>1</td>
<td>1,000</td>
<td>0.416</td>
<td>417</td>
</tr>
<tr>
<td>Phase 2 completes (45%)</td>
<td>4,000</td>
<td>1</td>
<td>4,000</td>
<td>1</td>
<td>4,000</td>
</tr>
<tr>
<td>Pretest/Study completes</td>
<td>6,650</td>
<td></td>
<td></td>
<td></td>
<td>5,496</td>
</tr>
</tbody>
</table>

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

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).


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Draft Docket: 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.