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. 2012–15105 Filed 6–19–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–12–12EF]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to 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

Evaluating the Effectiveness of Occupational Safety and Health Program Elements in the Wholesale Retail Trade Sector—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For the current study, the National Institute for Occupational Safety and Health (NIOSH) and the Ohio Bureau of Workers Compensation (OBWC) will collaborate to examine the association between survey-assessed Occupational Safety and Health (OSH) program elements (organizational policies, procedures, practices) and workers compensation (WC) injury/illness outcomes. The study will be conducted using a stratified sample of OBWC-insured wholesale/retail trade (WRT) firms. Crucial OSH program elements with particularly high impact on WC losses will be identified in this study and disseminated to the WRT sector.

There are expected to be up to 4,404 participants per year. Surveys will be administered twice to the same firms in successive years (e.g. from January–December 2013 and again from January–December 2014). An individual responsible for the OSH program at each firm will be asked to complete a survey that includes a background section related to respondent and company demographics and a main section where individuals will be asked to evaluate organizational metrics related to their firm's OSH program. The firm-level survey data will be linked to five years of retrospective injury and illness WC claims data and two years of prospective injury and illness WC claims data from OBWC to determine which organizational metrics are related to firm-level injury and illness WC claim rates. A nested study will ask multiple respondents at a subset of 60 firms to participate by completing surveys. A five-minute interview will be conducted with a 10% sample of non-responders (up to 792 individuals).

In order to maximize efficiency and reduce burden, a web-based survey is proposed for the majority (95%) of survey data collection. Collected information will be used to determine whether a significant relationship exists between self-reported firm OSH elements and firm WC outcomes while controlling for covariates. Once the study is completed, benchmarking reports about OSH elements that have the highest impact on WC losses in the WRT sector will be made available through the NIOSH–OBWC internet sites and peer-reviewed publications.

In summary, this study will determine the effectiveness of OSH program elements in the WRT sector and enable evidence-based prevention practices to be shared with the greatest audience possible. NIOSH expects to complete data collection in 2014. There is no cost to respondents other than their time. The total estimated annual burden hours are 1,681.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Safety and Health Managers	Occupational Safety and Health Program Survey Year 1 and Year 2.	4,404	1	20/60
	Informed Consent Form	4,404	1	2/60
	Non-Responder Interview	792	1	5/60

Kimberly S. Lane,

Deputy Director, Office of Science 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–2011–N–0568]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Disease Information in Branded Promotional Material

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 July 20, 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: Experimental Study: Disease Information in Branded Promotional Material.'' 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: Disease Information in Branded Promotional Material—(OMB Control Number 0910–New)

I. Regulatory Background

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(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 advertisements to contain accurate information about the benefits and risks of the drug advertised. Generally, the advertising must not be misleading about the effectiveness of the drug. Specifically, the ad must not contain a representation or suggestion that the drug is better than has been shown by substantial evidence or useful in a broader range of patients (Ref. 1). The regulations prohibit sponsors from, for example, disseminating promotional information that may broaden the indications of medications beyond the indication for which they have been approved.

Rationale: As a public health agency, FDA encourages the communication of accurate health messages about medical conditions and treatments. One way in which broad disease information is communicated to the public is through disease awareness communications.

Disease awareness communications are communications disseminated to consumers or health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or device or make any representation or suggestion concerning a particular drug or device. Help-seeking communications are disease awareness communications directed at consumers. FDA believes that disease awareness communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide, appropriate treatment. This is particularly important for under-diagnosed, under-treated health conditions, such as depression, hyperlipidemia, hypertension, osteoporosis, and diabetes. Unlike drug and device promotional labeling and prescription drug and restricted device advertising, disease awareness communications are not subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) and FDA regulations.''(Ref. 2)

Some research has shown that disease awareness advertising is viewed by consumers as more informative and containing less persuasive intent than full product advertising (Ref. 3).

Sponsors may choose to include disease information in their full product promotions. Such information is designed to educate the patient about his or her disease condition. However, in some cases a full description of the medical condition may include information about specific health outcomes that are not part of a drug's approved indication. The current project is designed to determine if providing such information in branded full product advertisements affects perceptions of the product.

When broad disease information accompanies or is included in an ad for a specific drug, consumers may mistakenly assume that the drug will address all of the potential consequences of the condition mentioned in the ad by making inferences that go beyond what is explicitly stated in an advertisement (Ref. 4). For example, the mention of diabetic retinopathy in an advertisement for a drug that lowers blood glucose may lead consumers to infer that the drug will prevent diabetic retinopathy, even if no direct claim is made. The advertisement may imply broader indications for the promoted drug than are warranted, leading consumers to infer effectiveness of the drug beyond the indication for which it was approved. If consumers are able to distinguish between disease information and product claims in an ad, then they will not be misled by the inclusion of disease information in a branded ad. If consumers are unable to distinguish these two, however, then consumers may be misled into believing that a particular drug is effective against long-term consequences. The current study will explore perceptions that result from including both disease information and promotional information about a specific drug in the same advertising piece.

Design Overview: We will investigate the effects of adding disease outcome information to branded promotional materials on consumer perceptions and understanding. This information will be examined in the context of direct-to-consumer prescription drug print advertisements. We hope to more readily generalize our findings by exploring the issues raised in this document in three medical conditions varying in severity and symptomatology: Chronic obstructive pulmonary disease (COPD), lymphoma, and anemia.

We plan to examine two variables in this study: the type of disease information (possible disease outcomes, versus non-outcome information, versus no information) and the format of the information (integrated with drug information versus separated). Some participants will see information about the disease that avoids discussion of disease outcomes the drug has not been shown to address, such as, ''Diabetes is a disease in which blood sugar can vary uncontrollably, leading to uncomfortable episodes of high or low blood sugar.'' Other participants will see disease information that mentions consequences of the disease that go beyond the indication of the advertised product, such as, ''Untreated diabetes can lead to blindness, amputation, and, in some cases, death.'' A third group will see drug product information only (no disease information). We will also examine the way in which the disease information is presented relative to the product claims in the piece by varying the format: Disease information mixed (integrated) with product claims versus disease information apart (separated) from product claims. We are exploring a number of different options for implementing these two variables. For example: alternating paragraphs of product and disease information, disease information on one page and product information on another page, use of different colors and fonts for disease and product information, and different visuals for disease and product information. Final format variations will be determined through pretesting. The pretests are designed only to make sure the particulars of the main study are implemented in the best way possible. The results of the pretests will not increase the burden on respondents in the main study, nor will the main study design change as a result of the pretests.

This study utilizes random assignment to conditions. Within

medical condition, participants will be randomly assigned to see one version of the ad. Participants will be recruited from a general population sample to control for prior knowledge about disease outcomes.

The design is described in Table 1:

TABLE 1—STUDY DESIGN

Medical condition	Disease information plus	Format of disease and product information		
		Integrated	Separated	Control (no disease info)
COPD	Non-outcome			
	Outcomes			
Lymphoma	Non-outcome			
	Outcomes			
Anemia	Non-outcome			
	Outcomes			

Data will be collected using an Internet protocol. Participants will be recruited from a general population sample to control for prior knowledge about disease outcomes. Because the task presumes basic reading abilities, all selected participants must speak and read English fluently. Participants must be 18 years or older. We will use ANOVAs and regressions to test hypotheses. Interviews are expected to last no more than 20 minutes. A total of 4,650 participants will be involved in the study. This will be a one-time (rather than annual) collection of information.

In the **Federal Register** of August 16, 2011 (76 FR 50737), FDA published a 60-day notice for public comment on the proposed collection of information. FDA received one public submission. In the following section, we outline the observations and suggestions raised in the submission and provide our responses.

(Comment 1) One statement suggested we add a multiple choice question to obtain a baseline of how consumers research information about their disease in other forms and if they are actively engaged in health care decisions.

(Response) We agree this question is interesting, but feel it is outside the scope of the current study. The purpose of the study is to examine how disease outcome and product information contained within the same piece influences perceptions of product benefit.

(Comment 2) One comment stated that the inclusion of the MedWatch reporting statement discloses the prescription status of the product and suggested rewording the question about the type of product being tested.

(Response) We have reworded the question, removing the choice options ''household cleaner'' and ''herbal supplement'' and added a ''don't know'' option.

(Comment 3) Two statements said that open-ended questions would result in subjective data interpretation and suggested either replacing them with closed-ended questions or deleting. These statements also suggested that procedures for coding, categorizing and analyzing verbatim responses be established in advance, and that comparable questions about both benefits and risks be included.

(Response) We have established baseline codes for the open-ended questions and included parallel questions to assess perceptions of benefits and risks (see draft questionnaire). Other codes will be established through pretesting. We will have two independent raters for coding and we will calculate inter-rater reliability. Disagreements between coders will be resolved through discussion. In addition, our open-ended questions are accompanied by closed-ended questions.

(Comment 4) One comment stated that those previously diagnosed with the medical condition may respond differently than the newly diagnosed.

(Response) We agree that length of diagnosis could impact responses to information. We are recruiting a general population sample and plan to use medical condition as a covariate. We have added a question to assess time since diagnosis among those who self-identify as having the condition of interest.

(Comment 5) The submission suggested deleting items: (1) Attitudes about the product; (2) multiple items measuring the same construct (risk, benefit); and (3) perceptions of the risk/benefit tradeoff.

(Response) We have addressed these suggestions in the following ways. We have deleted the questions measuring product attitudes. We believe that two questions measuring risk and benefits are necessary to assess the reliability (Ref. 5) of each construct and so have kept both questions. With regard to the final point, we agree that the risk/benefit ratio is different for each patient, but we also think that the perceived risk/benefit ratio for a product is influenced by the information presented in the ad. It is relevant here in that the risk/benefit assessment may be influenced by the perception that the disease outcome information is a product characteristic.

(Comment 6) One statement suggested deleting the questions related to behavioral intention, while another statement suggested expanding these questions.

(Response) As these statements are contradictory, we offer our reasoning behind including these questions. In an ideal situation, we would be able to measure actual behaviors that may result from exposure to a particular promotional campaign. Because we cannot do that, we propose to measure participants' intended behavior; that is, the likelihood that they would engage in specific outcome behaviors that may occur as a result of exposure to the product and disease information. This is in concordance with the recommendations of the November 17, 2011, meeting of the Risk Communication Advisory Committee, which suggested behavioral intention as an important variable to measure in research studies on promotion.

(Comment 7) One comment stated that the questions assessing recall included false benefit items but were not balanced with statements to recall true/factual disease awareness information and suggested including true statements from the disease awareness information.

(Response) Our use of the term ''false benefit'' in the questionnaire notes may have caused confusion. In the draft questionnaire, ''false benefit'' simply refers to disease characteristics that are not part of the product's indication. The purpose of this question is to first

determine which, if any, of the outcome claims are being interpreted by the participant as product benefits. Following this question is an open-ended question intended to measure what it was about the ad that suggested that (see questionnaire). We have revised the questionnaire notes to read ''outcome'' and ''non-outcome'' for clarity.

(Comment 8) One statement asked for more detail about the study design and stimuli layout and offered specific suggestions on variables to include in the study: Vary the presentation of the disease information using headers with and without disclaimers, use a control test ad with no headers, use branded colors, non-branded colors, etc. to maximize understanding of whether consumers are able to distinguish between disease information and product claims and whether the format enhances understanding.

(Response) We have included a description of the study design in both the 60-day and 30-day **Federal Register** notices. We are exploring a number of different options for implementing the layout of the stimuli. For example: Alternating paragraphs of product and disease information, disease information on one page and product information on another page, use of identical or different colors and fonts for disease and product information, and different visuals for disease and product information. Final format variations will be determined through pretesting. This is the first study of this issue and therefore we are focusing on a small number of variations. It is not feasible to include every possible variation. We appreciate the layout suggestions provided.

(Comment 9) One statement addressed the recruitment process, requesting that we disclose how participants will be recruited and recommending mall intercept recruitment because recruiting participants online may not be reflective of the consumer likely to observe print advertising.

(Response) We plan to recruit and conduct the study online to use our resources most efficiently.

(Comment 10) One statement asked for a rationale for our sample size.

(Response) We have provided a rationale for our sample size in the Power Analysis.

(Comment 11) One statement requested details on the assignment to conditions, saying it was unclear if the study will include a sufficiently stratified sample based on language abilities, preexisting knowledge/disease awareness, age, gender, etc.

(Response) Participants will be randomly assigned to conditions. An attempt will be made to have an equal number of males and females in each experimental cell. Approximately 20 percent of participants in each cell will have a high school education or less, with a range of education and race/ethnicity represented in each condition. The following screening criteria will be employed: participants must be age 18 and over, must not work for a pharmaceutical company, an advertising agency, a market research company, or be health care professionals.

(Comment 12) One statement asked that the screener specify if only those previously diagnosed with the condition will be eligible to participate, saying those previously diagnosed with the medical condition may engage differently than those who are recently diagnosed.

(Response) We agree that those who have the medical condition may react differently than those who do not. We plan to use diagnosis as a covariate in our analyses.

The total annual estimated burden imposed by this collection of information is 1,873 hours for this one-time collection.

The response burden chart is listed in table 2.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Sample outgo (pretests and main survey)	27,679				
Number of screener completes (35%)	9,688	1	9,688	2/60	323
Number eligible (80%)	7,750				
Number of completes, Pretests (60%)	900	1	900	20/60	300
Number of completes, Study (60%)	3,750	1	3,750	20/60	1,250
Number of pretest/study completes	4,650				
Total					1,873

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60''.

II. References

The following references have been placed on display in the Division of Dockets Management, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. See 21 CFR 202.1(e)(6): ''An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons if it: (i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of patients (as used in this section, *patients* means humans and in the case of veterinary drugs, other animals), safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii)(b) and (c) of this section) whether or not such representations are made by comparison with other drugs or treatments * * *''

2. Draft Guidance for Industry: 'Help-Seeking' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms'' (pg. 1). Available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf.* Last accessed June 8, 2012.

3. Lee-Wingate, S. and Xie, Y. (2010). Consumer perceptions of product-claim versus help-seeking direct-to-consumer advertising. ''International Journal of Pharmaceutical and Healthcare Marketing,'' 4(3), 232–246.

4. Burke, R. R., DeSarbo, W. S., Oliver, R. L., and Robertson, T. S. (1988). Deception by implication: An experimental investigation. ''Journal of Consumer Research,'' 14(4), 483–

494; Harris, R. J. (1977) Comprehension of pragmatic implication in advertising. ''Journal of Applied Psychology,'' 62, 603–608; Jacoby, J. and Hoyer, W. (1987). ''The comprehension and miscomprehension of print communications.'' New York: The Advertising Educational Foundation.

5. Guidance for Industry: Patient Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071975.pdf*. Last accessed November 16, 2011.

6. Transcript available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM283132.pdf*. Last accessed January 4, 2012.

Dated: June 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14989 Filed 6–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Secure Supply Chain Pilot Program

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 (the PRA).

DATES: Fax written comments on the collection of information by July 20, 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 title Secure Supply Chain Pilot Program. 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. PIFO–400W, Rockville, MD 20850, (301) 796–7651.

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: ''Secure Supply Chain Pilot Program.''

The Secure Supply Chain Pilot Program (SSCPP) is intended to assist FDA in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the Agency to focus its resources on imported drugs that fall outside the program and that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program.

Title: Secure Supply Chain Pilot Program.

Description of Respondents: Respondents to this collection of information are sponsors and foreign manufacturers of finished drug products and active pharmaceutical ingredients (APIs) intended for human use.

Burden Estimate: In the **Federal Register** of January 15, 2009 (74 FR 2605) (the January 2009 notice), FDA announced an opportunity for sponsors and foreign manufacturers of finished drug products and APIs intended for human use imported via a secure supply chain to apply to participate in a voluntary SSCPP to be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Office of Regulatory Affairs (ORA). The goal of the SSCPP is to allow FDA to determine the practicality of developing a secure supply chain program. The information obtained from this pilot program will assist FDA in its determination. An SSCPP would assist the Agency in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs by allowing the Agency to focus its resources on imported drugs outside the program that may pose such risks. Such a program would increase the likelihood of expedited entry for specific finished drug products and APIs imported into the United States that meet the criteria for selection under the program. A limited number of applications that meet criteria established by FDA will be selected by FDA based largely on information submitted in the SSCPP application.

Because there is information collection under the PRA associated with the SSCPP, this **Federal Register** notice is being issued as part of the process for OMB approval to collect this information. After OMB approval, FDA will accept applications to participate in the program and will select qualified applications. FDA will announce in the **Federal Register** OMB's approval, the date that applications may be submitted, and application submission procedures. FDA has considered all PRA and Non-PRA comments received. This FR notice responds only to the PRA-related comments.

The information collection associated with the SSCPP consists of the following:

(1) Secure Supply Chain Pilot Program application form. Proposed Form FDA 3676 will request the following: (a) Identification and contact information for sponsors and foreign manufacturers wishing to participate in the SSCPP; (b) information about each drug to be imported; (c) logistical information associated with the importation and a description of the process by which the drug will be brought into the United States; and (d) a description of procedures that the applicant will follow to remedy any deficiencies that FDA may identify with the importation, including recall procedures. A draft of proposed Form FDA 3676 may be obtained at *http://www.fda.gov/cder/fedreg/fda-3676.pdf,* or by calling (301) 796–7651. The SSCPP application form may not be submitted to FDA until OMB has approved the information collection associated with the SSCPP.

(2) Changes to information contained in the SSCPP. If there are changes to the information contained in the SSCPP application, then the applicant would be expected to submit to FDA a modified application detailing those changes and obtain FDA authorization before implementing them.

(3) FDA withdrawal of selection. If FDA withdraws its selection of an application from participating in the SSCPP, the applicant would be given an opportunity to provide information to FDA to show that the program's criteria are met and participation should continue or be resumed. FDA will consider and act on this information at its sole discretion.

(4) Recordkeeping requirements. Applicants will be expected to maintain records that confirm the information provided in their SSCPP applications and make these records available to FDA if requested. While these records must be maintained for the duration of the applicant's participation in the program, FDA requests that they be maintained and be readily available when requested by FDA for a period of at least 3 years after the pilot ends or the