

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Adults (40–79 years old)	Telephone Screener (Attachment 16)	1700	1	10/60 (0.17)	283
	Main Questionnaire (Attachment 6)	225	1	60/60 (1)	225
	Prostate Supplemental Questionnaire (Attachment 7).	125	1	30/60 (0.5)	63
	Liver Supplement (Attachment 8)	225	1	30/60 (0.5)	113
	Refusal Questionnaire Form (Attachment 21)	225	1	2/60 (0.03)	8
Totals	2500	692

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Glenwood E. Trivers or Elise Bowman, Center for Cancer Research, NCI, NIH, 37 Convent Drive Room 3060–C or 3060–A, Building 37, Bethesda, Maryland 30893–4258 or call non-toll-free number 301–496–2094 or 301–496–2090 or e-mail your request, including your address to *triversg@mail.nih.gov* or *bowmane@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 18, 2010.
Vivian Horovitch-Kelley
NCI Project Clearance Liaison, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0079]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Graphic Cigarette Warning Labels

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 September 24, 2010.

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 Graphic Cigarette Warning Labels.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug

Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@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 Graphic Cigarette Warning Labels—(OMB Control Number 0910–NEW)

Tobacco products are responsible for more than 440,000 deaths each year. The Centers for Disease Control and Prevention report that approximately 46 million U.S. adults smoke cigarettes in the United States, even though this behavior will result in death or disability for half of all regular users. Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total \$193 billion annually in medical expenditures and lost productivity. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time. One way to do this is through health warnings that describe and graphically depict the harm caused by cigarette use.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111–31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act, which amends section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), requires FDA to issue “regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).” FDA conducts research relating to tobacco products under its statutory authority in section

1103(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, to conduct research “relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out the act.” The study proposed here is an effort by FDA to collect data concerning graphic warnings on cigarette packages and their impact on consumer perceptions, attitudes, and behavior with respect to smoking.

The study, the Experimental Study of Graphic Cigarette Warning Labels, is a voluntary experimental survey of consumers. The purpose of the study is to assess the effectiveness of various graphic warnings on cigarette packs for achieving three communication goals: (1) Conveying information about various health risks of smoking, (2) encouraging cessation of smoking among current smokers, and (3) discouraging initiation of smoking among youth and former smokers. The study will collect data from various groups of consumers, including current smokers aged 13 years and older, former smokers aged 13 years and older, and non-smokers aged between 13 and 25 years who may be susceptible to initiation of smoking. The study goals are to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to graphic warning labels; (2) determine whether consumer responses to graphic warning labels differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of various graphic images associated with each of the nine warning statements specified in the Tobacco Control Act for achieving each of the communication goals. The information collected from the study is necessary to inform the agency’s efforts to implement the mandatory graphic warnings required by the Tobacco Control Act.

The experimental study data will be collected from participants of an Internet panel. Participation in the experimental study is voluntary.

In the **Federal Register** of February 22, 2010 (75 FR 7604), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five comments in response to the notice.

All five comments supported FDA’s proposal to sponsor consumer research to provide a scientific basis for regulations requiring color graphics to accompany the new statutory health warnings set forth in the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act.

One comment recommended that the FDA consider conducting followup assessments to determine whether the warnings are having their intended effects and, if not, to determine what revisions are needed.

FDA agrees that appropriate surveillance is important, and that the comment makes an excellent suggestion for future research.

Two comments recommended that FDA include information about cessation resources in the tested graphic warnings.

FDA will be testing a variety of different graphics that will vary in style and intensity. Some of the tested images will include information about cessation resources. Decisions about whether to include specific graphics containing cessation information in final regulations will be made after the results of the experimental study are available and these data will be a primary factor in the selection of images for final regulations.

One comment recommended that FDA use images that are medically accurate to avert claims that the graphics are deceptive to consumers and ensure that smokers are confident in the accuracy of the health information provided.

FDA agrees that it is important to ensure that the graphic health warnings convey accurate information about smoking risks to consumers. The data collected from the proposed research will provide important information to ensure that the graphic health warnings being tested do not elicit unintended responses from consumers.

One comment urged that FDA ensure that the questionnaire ask questions in an objective and unbiased manner.

FDA agrees with this recommendation and has designed a survey instrument that includes validated measures used in other research. Thus the questions are objective, unbiased, and reliably understood by respondents. In addition, FDA plans to conduct cognitive interviews prior to the experimental survey. These interviews will help identify any unanticipated problems consumers may have in understanding or responding to the questions in the survey.

One comment questioned the basic premise of requiring graphic health warnings, stating that international experience shows that graphic health warnings have not reduced smoking rates.

The purpose of this study is not to determine whether FDA should require graphic health warnings. Congress has already made that determination. Similarly, the purpose of this study is

not to determine the absolute effectiveness of graphic health warnings in terms of changing smoking behavior. Instead, the purpose of this study is to determine the relative efficacy of various graphic health warnings for conveying risk information to consumers and provide a scientific basis for FDA’s regulations for graphic health warnings as required by the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act.

One comment sought assurance that FDA will obtain appropriate parental consent and Institutional Review Board (IRB) approvals, especially with respect to the collection of information from adolescents.

FDA strongly agrees that appropriate parental consent and IRB approval is important and necessary. Such consent and approval will be obtained as part of the standard regulatory research process and before any collection of information.

One comment questioned FDA’s decision to use an Internet survey, especially with respect to the collection of information from adolescents, and recommended that FDA sponsor an in-person survey instead.

As indicated previously in this document, the purpose of this study is to assess the relative efficacy of various graphic health warnings. The use of an Internet-based panel to collect our experimental data is appropriate for this purpose. FDA believes that the Internet-based panel will provide the most efficient and practical methodology for collecting the data.

One comment also indicated that an Internet-based survey is not well-suited to analyzing health warnings because the health warnings under real world conditions appear on three-dimensional packages rather than on two-dimensional images on a computer screen. The comment recommended that FDA consider a prior mailing of realistic mockups of cigarette packages, which the participants could examine while taking the survey.

FDA agrees that it is important that survey participants view realistic images of the tested graphic health warnings on product packaging. The study is designed so that participants will view a three-dimensional animation of mockups of various graphic warnings on product packaging. Participants will be able to manipulate the animation during the survey to see the front, back, and sides of the package. We believe that this animation is sufficient to ensure that study participants view the tested graphic warnings under realistic conditions.

One comment recommended that FDA include a meaningful pretesting of the survey instrument, including the use of cognitive interviews.

FDA agrees that meaningful pretesting of the survey instrument is important, and plans both cognitive interviews and pretests. The cognitive interviews will help FDA evaluate and refine the draft questionnaire, and help to identify areas where the instrument is ambiguous, burdensome, or confusing. FDA will also conduct pretests of the algorithms and programs for respondent sampling, survey administration, and data collection.

One comment raised a number of individual concerns that the planned cross-sectional design of the proposed survey is not capable of providing information from which causal conclusions about the relationship between exposure to the graphic images and smoking behavior can be based. The comment also raised the concern that questions regarding intended actions about smoking cessation or smoking initiation are inadequate to demonstrate actual behavioral changes. To address these concerns, the comment recommended the use of a longitudinal design that monitors actual behavior over time.

The purpose of this study is not to determine the absolute effectiveness of graphic health warnings in terms of changing smoking behavior. Instead, as

indicated previously in this document, the purpose of the study is to determine the relative efficacy of various graphic health warnings for purposes of providing a scientific basis for FDA's regulations for graphic health warnings as required by the Federal Cigarette Labeling and Advertising Act, as amended by the Tobacco Control Act. A cross-sectional design is appropriate for this purpose.

In addition, FDA disagrees that questions concerning intentions to quit smoking or to not begin smoking are inappropriate. The more recent scientific literature shows that statements by smokers concerning their intentions to quit smoking are predictive of their making subsequent quit attempts (Ref. 1). Similarly, the scientific literature demonstrates that statements by children and adolescents concerning their intentions to smoke or not smoke are reliable predictors of subsequent smoking and precedes smoking initiation (Ref. 2).

One comment noted that it is important that the study be conducted in a manner that avoids question order bias.

FDA agrees that efforts must be taken to avoid any potential bias, and is confident that the study will be conducted in a manner that yields objective and reliable results. The planned cognitive interviews and pretests should help identify potential

problems with question order and allow FDA to address those concerns prior to the experimental survey.

One comment recommended that FDA use a research design that tests across subjects, rather than within subjects. The comment states that failure to use an across-subjects design will lead to an overestimate of the effects of bolder warnings.

FDA's proposed study employs a between-subjects design that will test across subjects.

One comment recommends that care be taken to avoid information overload, given the number of warning statements and images.

FDA agrees with the comment. The between-subjects design of the study will reduce the potential for information overload. Each treatment group of respondents will view and respond to one graphic warning label.

One comment also included comments on a separate **Federal Register** notice that sought public comment on a proposed FDA collection of information concerning the pretesting of tobacco communications, Docket No. FDA-2010-N-0084. That notice is not related to the information collection concerning graphic health warnings. Accordingly, those comments are not addressed in this document.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pre-test	60	1	60	0.25	15
Screener	36,000	1	36,000	0.016	600
Experimental Survey	23,400	1	23,400	0.25	5,850
Total					6,465

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pre-test of the study, estimated to last 15 minutes (0.25 hours), for a total of 15 hours. Approximately 36,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 600 hours. Eighteen thousand (18,000) respondents will complete the full study, estimated to last 15 minutes (0.25 hours) and approximately 5,400 of those respondents will complete an additional

survey 1 to 2 weeks following the original survey, estimated to last 15 minutes (0.25 hours), for a total of 5,850 hours. The total estimated burden is 6,465 hours. Burden hours exceed FDA's previous estimates published in the 60-day notice of this study. Additional hours are the result of an increase in respondent sample size. A larger sample size is required to ensure sufficient statistical power for analysis of the data.

References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**),

and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Zhou, X et al. "Attempts to quit smoking and relapse: Factors associated with success or failure from the ATTEMPT cohort study," *Addictive Behaviors*, 2009; 34: 365-373; Hyland A et al. (2006). "Individual-level predictors of cessation behaviours among participants in the International Tobacco Control (ITC) Four Country Survey," *Tobacco Control*, 15: iii83-iii94.

2. Hampson SE et al., "Predictors of the Development of Elementary-School Children's Intentions to Smoke Cigarettes: Hostility, Prototypes, and Subjective Norms," *Nicotine and Tobacco Research*, 2007 July; 9(7): 751-760; Wakefield, M. et al., "The role

of smoking intentions in predicting future smoking among youth: findings from the Monitoring the Future data," *Addiction* 2004 Jul; 99(7): 914–22; Pierce J, et al., "Validation of susceptibility as a predictor of which adolescents take up smoking in the United States," *Health Psychology*, 1996(Sept): 355–61.

Dated: August 20, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–21123 Filed 8–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–210]

A Review of Information Published Since 1995 on Coal Mine Dust Exposures and Associated Health Outcomes

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft Current Intelligence Bulletin entitled "A Review of Information Published Since 1995 on Coal Mine Dust Exposures and Associated Health Outcomes" now available for public comment. The draft document and instructions for submitting comments can be found at: <http://www.cdc.gov/niosh/docket/review/docket210/default.html>. This document updates and supports the coal mine dust Recommended Exposure Limit (REL) of 1 mg/m³ that was recommended in the 1995 document, "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust, (1995–106)" which can be viewed at: <http://www.cdc.gov/niosh/95-106.html>.

This guidance does not have the force and effect of the law.

Public Comment Period: Comments must be received by September 24, 2010.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, identified by Docket Number NIOSH–210, by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

- **Facsimile:** (513) 533–8285.

- **E-mail:** nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to Docket Number NIOSH–210.

FOR FURTHER INFORMATION CONTACT:

Michael D. Attfield, Ph.D., telephone (304) 285–5737, e-mail mda1@cdc.gov or Eileen Storey, M.D., telephone (304) 285–6382, e-mail eps4@cdc.gov, NIOSH, 1095 Willowdale Road, Morgantown, WV 26505.

Dated: August 17, 2010.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2010–21187 Filed 8–24–10; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft National Conversation on Public Health and Chemical Exposures Work Group Reports; Opportunity for Public Comment

AGENCY: Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The National Conversation on Public Health and Chemical Exposures is a collaborative initiative through which many organizations and individuals are helping develop an action agenda for strengthening the nation's approach to protecting the public's health from harmful chemical exposures. This notice announces the availability of draft National Conversation work group reports for public review and comment. CDC/

ATSDR has partnered with RESOLVE, a non-profit independent consensus-building organization, to manage aspects of the National Conversation project. RESOLVE is convening the National Conversation Leadership Council and facilitating the work group process.

DATES: Draft work group reports will be available on or about September 7, 2010. In order to be considered, comments must be received within 14 days of the reports being posted. The public comment period is anticipated to close September 20, 2010. Comments received after the close of the comment period will be considered to the fullest extent possible.

ADDRESSES: Draft work group reports will be available on RESOLVE's Web site at <http://www.resolve.org/nationalconversation>. Those interested in submitting comments are encouraged to submit them through that Web site. Comments can also be submitted by e-mail to nccomments@resolve.org. Please indicate in the e-mail subject line the name of the work group report that your comments address (e.g. "Comments on Monitoring Work Group Report"). Comments can be submitted by mail to National Conversation c/o RESOLVE, Inc. 1255 23rd Street, NW., Suite 875, Washington, DC 20037 or by fax attention to Jason Gershowitz at 202–338–1264.

FOR FURTHER INFORMATION CONTACT:

Please direct questions about the National Conversation project to CDC/ATSDR by e-mail at nationalconversation@cdc.gov, phone at 770–488–0604, or mail at National Conversation, CDC/ATSDR, 4770 Buford Hwy, NE., MS F–61, Atlanta, GA 30341.

SUPPLEMENTARY INFORMATION: The National Conversation project includes a Leadership Council, which will author the action agenda, and six work groups, formed to research and make recommendations on the following cross-cutting public health and chemical exposures issues:

- Monitoring
- Scientific Understanding
- Policies and Practices
- Chemical Emergencies
- Serving Communities
- Education and Communication

Following the public comment period, National Conversation work groups will finalize their reports during the fall of 2010. The National Conversation Leadership Council will draw on work group reports and the results of public input received through Web dialogues, community conversations, and stakeholder forums