4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0867]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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 on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents--(OMB Control Number 0910-NEW)

The Tobacco Control Act (Public Law 111-31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 904(d)(1) of the FD&C Act (21 U.S.C. 387d(d)(1)) states, "Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful or potentially harmful constituents] established under [section 904(e)]" of the FD&C Act. Section 904(e) of the FD&C Act (21 U.S.C. 387d(e)) directs FDA to establish "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand, and by quantity in each brand and subbrand." On January 31, 2011, FDA announced the availability of a final guidance representing the Agency's

current thinking on the meaning of the term "harmful and potentially harmful constituent" (see 76 FR 5387, January 31, 2011). On April 3, 2012, FDA published a notice in the Federal Register establishing a list of the harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke (see 77 FR 20034) as required by section 904(e) of the FD&C Act.

FDA intends to conduct research with consumers to help inform decisions about how to implement section 904(d)(1) of the FD&C Act and to provide information about how consumers understand information about HPHCs. The primary research goal is to evaluate the impact of different list formats on the public's ability to understand HPHC information. The impact of different list formats will be measured by evaluating respondents' understanding of certain communication objectives addressed in this document. Secondary outcomes of interest include measuring effects of different list formats upon respondents' susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, and risk perceptions about tobacco use.

FDA proposes to conduct an experimental study with current smokers aged 13 years and older, smokeless tobacco users aged 18 years and older, and nonsmokers aged between 13 and 17 years who may be susceptible to initiation of smoking. Data will be collected from members of an Internet panel. Participation in the experimental study is voluntary. The information collected from the study is necessary to inform the Agency's efforts to implement the requirement of the FD&C Act to place on public display a list of HPHCs in tobacco products and tobacco smoke in a format that is understandable and not misleading to a lay person, and is expected to provide information that may inform Agency communications about HPHCs. The data obtained from this study is one factor that will be used to inform FDA's decisionmaking

regarding the public display of the list of HPHCs required under section 904(d)(1). By evaluating respondents' understanding of the concepts listed in this document we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements.

In the Federal Register of December 14, 2011 (76 FR 77837), FDA published a 60-day notice requesting public comment on its proposed collection of information. FDA received eight comments that were PRA related, which required a total of 10 responses.

(Comment 1) One comment recommended that the study examine the effects of HPHC lists for smokeless tobacco products as well as for cigarettes.

(Response) FDA agrees. The proposed study will assess the impact of different HPHC list formats for three classes of tobacco products (cigarettes, smokeless tobacco products, and roll-your-own tobacco) on consumer comprehension, beliefs, perceptions, and other precursors to behavior.

(Comment 2) One comment encouraged FDA to recruit participants from multiple demographic groups.

(Response) FDA agrees that it is important to include a diverse group of individuals in the study and plans to include a demographically diverse sample of respondents drawn from four primary groups: Adult smoker, young adult smoker, youth smoker, and youth at risk for tobacco initiation.

(Comment 3) One comment recommended that FDA compare consumer responses to the HPHC lists against those that do not view an HPHC list. This would facilitate an evaluation of what consumers may understand, believe, perceive, or do in the absence of the HPHC list.

(Response) FDA agrees. Within each sample group, respondents will be randomly assigned to one of the treatment groups that view an HPHC list format or to a control group that

does not view a list. Some of the formats will include additional information to provide context for the HPHC lists to the consumer. The effects of each list will be determined during analysis through a comparison of responses between treatment and control groups.

(Comment 4) One comment cautioned FDA to consider the utility of including underage nonsmokers in the experimental study.

(Response) FDA has considered the utility of including under age nonsmokers in the study. FDA believes it is important to consider the risks and benefits of the HPHC lists to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products. Although FDA does not believe that there is any information on the HPHC list that would encourage nonusers to initiate tobacco use, one of the secondary outcomes it is to assess the effects of the provision of HPHC lists on youth that do not currently use tobacco products but who may be at risk of initiating the use of tobacco products.

(Comment 5) One comment recommended that the data collected from the users of smokeless tobacco products be analyzed separately from cigarette smokers.

(Response) FDA agrees. FDA will collect data on the use of tobacco products. The study now includes a sample of adult smokeless tobacco users aged 18 years and older. The data from those who use smokeless products will be analyzed separately.

(Comment 6) Three comments provided recommendations on pretesting the information provided in the lists with target audiences prior to implementation. One of these comments suggested that FDA use open-ended questions to allow respondents to say/type what they understand each statement to mean.

(Response) FDA agrees. FDA intends to conduct cognitive interviews with individuals to assess comprehension of the test instrument and certain aspects of the list formats prior to conducting the study. Individuals will be asked open-ended questions during the cognitive testing of the list formats and the survey questions.

(Comment 7) Two comments encouraged FDA to provide additional information for public comment during the development of the study including the list formats, study design, and measurement plans for the listed unintended consequences.

(Response) The study protocol, list formats, and the survey questionnaire are available for review and public comment upon request. To request this information see the FOR FURTHER INFORMATION CONTACT section of this document.

(Comment 8) One commenter stated that the HPHC list could not fully inform consumers because the list is not complete, and the consumer would not understand that the listed quantity of the chemicals were based on machine testing and therefore are not necessarily a reflection of human use. Other comments argued there was a high likelihood that consumers will conclude that lower numbers or fewer constituents means a product is less risky. They also suggested the need to have disclaimers that provide information to counter potential misunderstandings.

(Response) FDA agrees that the list format may have the potential to mislead consumers, which is why FDA plans to conduct an experiment with consumers to assess the impact of various formats of the HPHC lists on consumer comprehension and precursors to behavior, such as beliefs, attitudes, and intentions. Some of the list formats to be included in the study will contain additional text and graphics to convey other information to consumers that may not be evident from a list of chemicals and numerical values. The study will assess various formats for conveying the communication goals enumerated in this document, such as uncertainty about the

information contained in the list; that other relationships between the constituents in tobacco products and health problems may be discovered in the future; that the values are the results of machine testing; and that exposure to the chemicals also depends on other factors, such as the variability of human use.

FDA's proposed study will also assess each list's potential for increasing the likelihood that consumers will conclude that lower numbers or fewer constituents imply that a tobacco product is less risky. To evaluate whether the lists encourage consumers to compare the relative risks of products, the study will include measures, such as whether consumers comprehend that the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem, and the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem.

(Comment 9) Two comments stressed the importance of using clear language with one suggesting that information be written at a fifth grade reading level. They also recommended FDA consider the impact of color, font type, and font size on consumer comprehension.

(Response) FDA intends to use plain language, where additional information is provided, and to select colors, font type, and font size that are likely to improve consumer comprehension.

(Comment 10) One commenter suggested FDA prioritize the communication objectives to facilitate evaluation of study results.

(Response) FDA agrees that a prioritization of the communication objectives may facilitate the evaluation of the results. At this time, FDA proposes a study to test the impact of various HPHC list formats on consumer comprehension of the communication objectives, although it is unlikely that a single format will be completely successful at meeting all of those objectives.

Based on comments received and preliminary qualitative research[1], FDA has refined the communication objectives listed in the Federal Register of December 14, 2011 (76 FR 77837) to the following: (1) The chemicals come from the tobacco leaf itself and different parts of a tobacco product, such as the tobacco smoke, glues, inks, paper, and additives; (2) for smokeless products, many of the chemicals come from the tobacco leaf itself; for smoked products, many of the chemicals come from burning the tobacco leaf; (3) tobacco companies are required to test their tobacco products and smoke for the chemicals on the list and report the amounts to FDA; (4) science has linked the chemicals on these lists to health problems or potential health problems; (5) these lists do not necessarily identify all of the health problems that may be caused by the tobacco product; (6) these lists do not necessarily include all of the chemicals in the tobacco product that may be harmful; (7) the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (8) the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; and (9) when a chemical is listed without a quantity it may mean that the chemical was not detected or the information is not currently available.

The remaining comments were unresponsive to the 60-day Federal Register notice. These comments were related to the development of an accompanying education campaign; the development of a Web site for consumers to get additional information; the provision of HPHC information on the packages of tobacco products; the use of claims by tobacco manufacturers, such as "all natural" or "no additives"; and the conformance of tobacco manufacturers and retailers to section 911 of the FD&C Act (21 U.S.C. 387k) regarding modified risk claims.

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

[1] OMB control number 0910-0674.

Table 1.--Estimated Annual Reporting Burden[1]					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pretest	60	1	60	0.5	30
Screener	10,000	1	10,000	0.0167	167
Experimental Survey	3,150	1	3,150	0.5	1,575
Total					1,772
[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 pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 10,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.0167 hours), for a total of 167 hours. Three thousand one hundred and fifty respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,575 hours. The total estimated burden is 1,772 hours.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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