Experimental Study on the Presentation of Harmful and Potentially Harmful Tobacco Constituents

0910-NEW

SUPPORTING STATEMENT

The purpose of this submission is to request OMB approval to conduct an experimental study to help inform FDA decisions about how to implement section 904(d)(1) of the Food Drug & Cosmetic Act (FD&C Act or the Act) and to provide information about how consumers understand information about Harmful and Potentially Harmful Constituents (HPHCs) in tobacco products.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act (Public Law 111-31) amends 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 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 Act. Section 904(e) of the FD&C Act 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). 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).

FDA's Center for Tobacco Products requires data on how consumers may respond to information about HPHCs in order to determine the appropriate format of the HPHC list provided to the public.

2. Purpose and Use of the Information Collection

FDA's Center for Tobacco Products will conduct an experimental study to help inform decisions about how to implement section 904(d)(1) of the Act and to provide information about how consumers understand information about HPHCs. The established list of HPHCs (see 77 FR 20034) contains complex scientific information that may be difficult for consumers to understand, therefore making the information potentially misleading. Section 904(d)(1) requires a version of this list be made available to the public. The Act states that this list must be "understood and not misleading to a lay person." The research goals are to evaluate the impact of different list formats on the public's ability to understand HPHC information, and to assess the potential impact on consumer behavior from exposure to the list.

The impact of different list formats on comprehension will be evaluated by measuring respondents' understanding of the following concepts: (1) the chemicals come from the tobacco leaf itself and from 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 the 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; (9) when a chemical is listed without a quantity it may mean: the chemical was not detected or the information is not currently available.

The potential impact of different list formats on consumer behavior will be evaluated by measuring the exposure to a list on susceptibility to initiation of tobacco use, motivation and confidence to quit using tobacco, and risk perceptions about tobacco use.

The measures for identifying youth at risk for smoking initiation were developed and tested for reliability and validity identified by John Pierce [1]. These measures have been used extensively by tobacco researchers in experiments and surveys over the past decade.

3. Use of Improved Information Technology and Burden Reduction

The study will be administered over the internet. Respondents will view a list and respond to questions using a web-based survey on their personal computers. Web-based surveys reduce respondent burden; minimize possible administration errors; and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared to face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. No comparable data have been collected by any other entities. The information collected from the study will inform the Agency's efforts to implement the publicly available list of HPHCs as required by law, in particular, by providing data that will assist in the development of a format for the list that is "understandable and not misleading to a lay person."

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection of information.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. The collection of information will provide important data needed for federal policy makers to make science-based decisions concerning the language

[1] Pierce, John, et al. 1996, Validation of Susceptibility as a Predictor of Which Adolescents Take Up Smoking in the United States, Health Psychology, 15(5), pp.355-361.

and format to be used to develop the publically available list of HPHCs required in the Tobacco Control Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection that would be inconsistent with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the FEDERAL REGISTER of December 14, 2011 (76 FR 77837), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 11 comments, eight which were were PRA realted in response to the notice.

(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-you-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 plan 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 non-smokers in the experimental study.

(Response) FDA has considered the utility of including under age non-smokers 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 non-users 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 use of tobacco products. The study now includes a sample of adult smokeless tobacco users ages 18 years and older. The data from those who use smokeless products will be analyzed separately.

(Comment 6) Three comments provided recommendations on pre-testing 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.

(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 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 below, 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 and font type and size on consumer comprehension.

(Response) FDA intends to use plain language, where additional information is provided, and to select colors, font type and 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.

9. Explanation of Any Payment or Gift to Respondents

The study respondents will be drawn from an online survey panel maintained by e-Rewards. E-Rewards provides its Internet panel members with a token incentive as part of their continuous participation in the Internet panel. Panel members earn e-Rewards currency for their participation in research surveys. The appropriate incentive that panel members receive for participation is based on an approximate length of the survey. Members can redeem their earned currency for a variety of valuable rewards that are of interest to them. Some examples of incentive partners include Pizza Hut, Best Buy, JCPenney's, Macy's, American Airlines, Hertz, Target, iTunes, and various publication companies for magazine subscriptions, among others. There is no additional payment or gift associated with participation in the study proposed here.

10. Assurance of Privacy Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain private. The study instrument will contain a statement that responses will be kept Private. Private information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Identifying information will not be included in the data files delivered by contractors to the agency.

Privacy will be assured by using independent contractors, RTI and e-Rewards, to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The contractors will only share data and/or information with FDA in an aggregated form or format, which does not permit FDA to identify individual respondents.

Neither e-Rewards nor RTI will share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the data files delivered to the agency. FDA and RTI will receive data for analysis in aggregate form. Although e-Rewards retains contact information on participants for honoraria purposes, individually identifiable information is not shared with anyone, including FDA and RTI; it is stored separately from the survey data file and is not linked in any way to participant responses.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. E-Rewards takes the following security measures to ensure separation between respondents' identity and their survey data. First, the survey instrument has no personally identifying information (PII) on it. No respondent name,

address, email address, phone number or any other kind of PII appears on the survey. The only way a survey is identified is with a digital identification number. Second, while the invitation method, whether email, mail or direct mail will inherently have PII information included, this will not be combined with survey responses, so the responses from the survey are not linked to the PII. Third, screener data shall be considered part of the survey data. E-Rewards will provide the results of the screener questions for all panelists, regardless of whether they qualify for the study. However, e-Rewards will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, e-Rewards will retain study records for the duration of the study. Upon final delivery of data files to RTI and completion of the project, e-Rewards will destroy all study records including data files upon request. E-Rewards will not be able to supply or access this information for any reason, even at the request of RTI, once destroyed. Finally, data coming directly from the survey engine are stored in a proprietary database. While this data is not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by e-Rewards will be sent via encrypted files.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

With regard to information systems being FISMA and FIPS compliant, the primary risk for subjects and the investigator / sponsor when using the online questionnaire study is the potential for inadvertent breach of privacy and confidentiality of the data. The protocol includes physical data security, good information management practices and computer processes for data security ((e.g., password protections, access granted only per need to know, encryption of transferred data) following DHHS and FDA regulations and policies as well as the Council of American Survey Research Organizations® Code of Standards and Ethics for Survey Research. The protocol states that the "data coming directly from the survey engine are stored in a proprietary database. While this data is not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. We understand that stored data should be encrypted and requested the Sponsor to provide additional information about data security for this study.

11. <u>Justification for Sensitive Questions</u>

The public display of the list of HPHC required under section 904(d)(1) is not restricted to adults thus, it is important to understand youth responses to the HPHC information. In order to identify those youth at risk of smoking or already smoking we need to ask the youth potentially sensitive questions about tobacco use. These questions are potentially sensitive because tobacco use among youth under 18 years of age is illegal in a few states and sales to youth under 18 years of age is illegal in all states.

To alleviate any potential concern for the youth, we will take all necessary measures to ensure privacy. Also, no personal identifying information will be attached to the data used for analysis – e-Rewards keeps personal identifying information to invite youth to participate in

surveys but this information will not be shared with RTI (this restriction is stated in the sub-contract between RTI and e-Rewards).

E-Rewards has a standing panel of youth ages 13-17 form which our sample will be recruited. The u.talk.back® panel was created specifically to reach children aged 13-17 years old directly, without parental involvement. The Federal law protecting children, Children's Online Privacy Protection Act (COPPA), does not restrict this type of activity for children aged 13 years old and older. No personally identifying information will be released, per the u.talk.back® member and privacy agreements (http://www.utalkback.com/privacypolicy.do). In summary, e-Rewards' activities for this study will be fully compliant not only with the Federal Law, but with the Council of American Survey Research Organizations® (CASRO) Code of Standards and Ethics for Survey Research, a tough, internationally-cited set of standards, which has long been the benchmark for the industry.

E-Rewards' invitation to youth does encourage parents to know about and approve of youth involvement in the panel and surveys. However, no active parental consent is required or requested. For this study, when the youth are invited to join our specific survey, both parental consent and youth assent will be requested and required. In the invitation for our specific study it will be emphasized that youth responses are strictly private and that youth will be instructed to NOT take the survey under their parents' supervision nor to share their answers or opinions with their parents. We will emphasize to the youth and parents that will want to encourage honest responses to the questions so that we can measure a valid youth response to the HPHC list formats.

FDA does not have plans to integrate state of residence into the analysis of sample selection. There will be random assignment to condition, so we do not believe that participants' states of residence would have an effect on the results that would require alterations to the analysis or sample selection plans. This is a similar approach as taken in past studies conducted by FDA, such as the Experimental Study of Graphic Health Warnings (OMB No. 0910-0668).

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. The estimated total hour burden of the collection of information is 1,772 hours (Table 1). Sixty panel members will take part in a pre-test 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.

Table 1. Estimated Annual Reporting Burden

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Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours

Pre-test	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	13,210				1,772

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $28,352 [1,772 hrs. x $16/hr (the 2008 median wage rate in the U.S.) [2]].

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

All respondent burden is reflected in A12. There are no capital, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to Federal Government

The estimated total cost to the Federal Government for this information collection is $302,949. The costs arise from the time spent by the contractor to assist in the development and conduct of the collection of information, analysis of the data, and the development of the various study stimuli depicting the HPHCs in tobacco products.

15. Explanation for Program Changes or Adjustments

This is a new data collection. There are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to inform the Agency's about how to implement section 904(d)(1) of the FD&C Act by evaluating the impact of different list formats on the public's ability to understand HPHC information, and to assess the potential for certain unintended consequences resulting from exposure to the lists. The purpose of tabulation is to qualitatively analyze the data and summarize findings to meet informational needs. The data analysis will include basic summary statistics, including means and frequencies of variables of interest. In addition, commonly accepted statistical techniques, such as descriptive analysis, analysis-of-variance (ANOVA), and regression will be used to analyze the experimental data.

Table 2. Project Schedule

[2] http://www.bls.gov/oes/2008/may/oes_nat.htm#b00-0000.

Activity	Date
Conduct pretests and finalize questionnaire	Within 14 working days following OMB approval
Conduct Internet Experimental Survey	Within 14 working days of approval of final questionnaire
Receive data files and syntax files	Within 45 working days of approval of final questionnaire
Receive methodology report	Within 45 working days of end of data collection

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site. In describing the information collection, FDA will clearly acknowledge that the data does not provide nationally representative estimates.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.