DATA TO SUPPORT COMMUNICATIONS TO EDUCATE CONSUMERS ON HOW TO SAFELY PURCHASE DRUGS ONLINE

SUPPORTING STATEMENT A

Food and Drug Administration
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Clearance of FDA "DATA TO SUPPPORT COMMUNICATIONS TO EDUCATE CONSUMERS ON HOW TO SAFELY PURCHASE DRUGS ONLINE"

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB

Through HHS Reports Clearance Officer_____

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) is seeking a clearance from OMB to conduct "Data to Support Communications to Educate Consumers on how to Safely Purchase Drugs Online."

FDA has identified significant public health risks to consumers who buy drugs from illegal websites because the products could have too much, too little, or contain the wrong active ingredient or dangerous ingredients. FDA, along with the Drug Enforcement Agency and multiple other state, national, and international organizations, regulates online pharmacies based on applicable laws. Although these organizations have helped make the U.S. pharmaceutical distribution system one of the safest in the world, the proliferation of online pharmacies has contributed to a rise in counterfeit or otherwise substandard drugs on the global market. To protect American consumers from the increasing threat of rogue online pharmacies, FDA is developing an integrated public outreach campaign to educate consumers on how to safely purchase drugs online.

To better guide and assess this campaign, FDA wishes to obtain a baseline of the target audience's knowledge, attitudes, and practices with regard to online pharmacies, and then to collect ongoing data for tracking progress against the campaign's objectives. This data collection activity will benefit the public health in two ways. First, it will provide FDA with critical information needed about the target audience to determine gaps in consumer knowledge, and their ongoing communications needs. As baseline testing, it will also allow FDA to assess changes in awareness of risks and benefits that may be associated with FDA messages and materials. This will help FDA design and evaluate effective communication strategies and avoid potentially risky, unintended consequences of problematic communications.

The requested clearance for evaluating consumer knowledge, attitudes, and practices around the purchasing of prescription drugs online seeks approval for a three year clearance of a self-administered, electronically delivered survey. Total annual respondent burden is calculated at 833.33 hours. FDA plans to use the data collected under this clearance to inform and evaluate its communications campaigns around the purchase of prescription medicines from online

pharmacies. The data will not be used for the purposes of making policy or regulatory decisions. Thank you in advance for your consideration.

Table of Contents

SUPPORTING STATEMENT

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

Sections 1003(d)(2)(C) and (D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 393) (Attachment 1) authorize FDA to conduct educational and public information programs and conduct research relating to its responsibilities. To do this effectively, FDA must conduct research and studies relating to health information, as authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) (Attachment 2).

Consumers are increasingly turning to the Internet to purchase prescription drugs because of the convenience, cost, and privacy. Unfortunately, as of July 2010, only 4 percent of websites reviewed by the National Association of Boards of Pharmacy appear to be in compliance with pharmacy laws and practice standards. Recent studies indicate that the majority of people with even some college education are unable to detect multiple untrustworthy features of illegal online pharmacies. FDA has identified significant public health risks to consumers who buy drugs from these illegal websites. The products may be counterfeit or substandard and therefore dangerous if they contain harmful ingredients or too much, too little, or the wrong active ingredient. To educate consumers on how to safely purchase drugs online, FDA enlisted Booz Allen Hamilton to develop and implement an integrated public outreach campaign. This campaign will inform the public of the risks of buying from illegal online pharmacies, educate consumers on the indicators of a legal or illegal online pharmacy, and teach consumers how to safely purchase drugs online.

FDA wants to ensure that the public outreach campaign has the highest potential of being received, understood, and accepted by the intended audience; therefore, FDA wishes to conduct a survey focused on purchasing from online pharmacies. The survey will collect quantitative data to serve as a baseline for evaluating campaign activities, and to aid in guiding and evaluating ongoing communications. In any communications campaign, understanding the target audience with respect to the campaign's goals at the beginning of the campaign is vital to successfully evaluating progress. Collecting baseline data will provide an understanding of what consumers currently know about safely buying prescription drugs online. This baseline will then serve as a starting point from which communications materials will be evaluated to ensure that they are addressing consumers' problems appropriately. Ultimately, doing this will maximize the effectiveness of FDA's outreach campaign.

Likewise, in order to evaluate ongoing progress toward and success in achieving goals, routine measurement of the target audience is needed. FDA wishes to conduct this survey yearly to evaluate the extent to which messages are effectively reaching and affecting the target audience. By evaluating annual data, FDA may be able to gauge the extent to which consumers are increasing their knowledge about safely purchasing prescription drugs online. Only through these types of ongoing evaluations can FDA track progress toward their goals, a necessary piece of any truly successful communications campaign. In addition, yearly surveys will allow us to

examine changes to the target audience's understanding and their methods for receiving information. This knowledge may help FDA adjust messages and strategies as audience characteristics change.

Conducting this survey also aligns with the major objective set forth by the Department of Health and Human Services (DHHS) to increase the proportion of health communication activities that include research and evaluation.[1] Evaluation of outreach campaigns also aligns with specific FDA objectives. Recently, FDA's Commissioner asserted that "one of the greatest challenges facing any public health agency is that of risk communication."[2] To that end, FDA has developed a strategic plan for risk communication. A major initiative of the strategic plan is the goal of strengthening the science that supports effective communication. By identifying gaps in key areas of public health knowledge, evaluating the effectiveness of communication messages, and integrating information gained through research/evaluation into practice, FDA will help ensure that the public has the information they need about FDA-regulated products, including prescription drugs purchased online.

For all these reasons, FDA requests OMB approval for a clearance to collect information related to consumer knowledge, attitudes, and practices about online purchasing of prescription drugs. FDA will utilize best practices for effective health communication research set forth by other Department of Health and Human Services agencies such as the National Cancer Institute.[3]

FDA requests approval to conduct a survey once every year for three (3) years, using the methods described in section B with respondents from the target audience. The total number of respondent burden hours will not exceed 1,650 hours annually for a total of 4,950 burden hours over three years. FDA will send OMB an annual report at the end of each year summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

A.2. Purpose and Use of the Information

FDA will use the data collected under this clearance to inform and evaluate its integrated outreach campaign designed to help consumers safely purchase drugs online. FDA expects the data to provide a baseline the target audience and track ongoing progress toward its online pharmacy campaign goals and objectives. FDA also plans to use the data to help tailor print, broadcast, and electronic media communications to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The data collected will provide quantitative information about target audiences – their knowledge, attitudes, and practices – that is critical to evaluating communication effectiveness.

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[1] U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000.

[2] Hamburg, M.A., & Sharfstein, J.M. The FDA as a Public Health Agency. New England Journal of Medicine, 360 (24), 2493-2495, June 11, 2009.

[3] National Cancer Institute (NCI). Making Health Communications Work: A planner's guide, Pink Book. Pub. No. T068. Washington, DC: U.S. Department of Health and Human Services (HHS), August 2004.

FDA must explore consumers' beliefs and perceptions about online pharmacy safety and use this information to inform the outreach campaign for ongoing success. To effectively inform consumers about the risks of online pharmacies and educate people on how to safely purchase prescription medications online, FDA must understand critical influences on people's decision-making process when choosing to purchase from online pharmacies. Quantitative information on decision-making processes will also give FDA a better understanding of the changing needs of its target audience. Guiding research questions are:

1. What proportion of Internet users is currently putting their health at risk by using rogue online pharmacies?
2. What proportion is potentially at risk?
3. What are the characteristics of these groups? How do they differ from those who are more knowledgeable about health risks posed by rogue online pharmacies?
4. What channels of communication work best for sending messages to those at risk?
5. What current information interventions or campaigns are recalled by participants?
6. [in possible future data collection waves] Has the FDA communication campaign raised awareness of health risks associated with using rogue online pharmacies among populations at risk?

Data will be analyzed using procedures such as cluster analysis to identify sub-groups of current or potential users of illegal online pharmacies. A logistical regression analysis will be used to model the likelihood of purchasing medicine online from illegal sources as a function of a number of different variables. Separate models will use as the dependent variable whether or not respondents have ever ordered prescription drugs online from illegal sites, and whether they have considered future purchases from illegal sites. The predictive and control variables will fall into several categories:

- Demographic & socio-economic: Gender, race, age, parental status, educational attainment, region of residence, and marital status
- General attitudes and behaviors toward shopping online: Convenience, time saving, cost saving, complexity, concerns around sharing credit card and personal information online
- Attitudes toward ordering prescription medicine online: Convenience, time saving, cost reduction, improved access to records, likelihood of errors, speed of fulfillment, around fraud, sharing credit card and personal information online
- Use and access to technology: Access to broadband Internet at home, work, or elsewhere, telephone services
- Favored methods of obtaining information about purchasing prescription medicine online: Providers, pharmacists, insurance providers, friends, various Internet sources, and various news sources
- Health and use of prescription medicines: Self-reported health status, number of prescriptions taken regularly

The models will permit analysis of the change in the probability that a user will buy prescription medicines online, given a change in the variable in question (e.g., the respondent's assessment of

buying prescription medicine's online as a cost saving method) while holding all other variables constant.

A.3. Use of Information Technology and Burden Reduction

The information will be collected through electronically delivered self-administered surveys. Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing maximally efficient.

Since the respondent pool is American adults who use the Internet, this study is well suited to the use of a Web-based survey. The sample will be restricted to adults residing in the U.S. With Web-based surveys, respondents complete an on-line survey and then submit the data electronically over the Internet. Web surveys reduce respondent burden because respondents can access and respond to the survey at a time and place convenient to them. Closed-ended questions (e.g., multiple-choice items, Likert scales) will be employed whenever possible.

A.4. Efforts to Identify Duplication and Use of Similar Information

FDA conducted a comprehensive review of existing literature to avoid duplication of research. We searched PubMed for relevant material published from 2004 to 2010 and LexisNexis for materials published within the last year. Researchers scanned the titles and summaries to identify articles related to consumers who wish to safely purchase drugs online (prescription drug abuse was intentionally left out). A total of 1,507 titles were scanned and 112 articles reviewed in detail. Although one study examined college students' awareness of risk factors of rogue online pharmacies, we found no large-scale surveys of consumers in general that examined knowledge, attitudes, and practices toward online pharmacy purchases. The survey of approximately 2000 college students was informative in that it found that at least 25 percent were unable to detect signs of risk from websites that were fabricated with typical elements from rogue pharmacy sites. The authors note: "If even college-educated individuals and those with specialized training in health-related sciences are enticed by low price tags and unsubstantiated claims offered by rogue online sellers of prescription drugs, then risks of purchasing drugs online could be even greater for America's most vulnerable, such as less educated patients without prescription drug coverage whose failing health necessitates the use of multiple expensive drugs." These observations strengthen the need for collecting information from the general population in order to profile those at risk and develop effective educational interventions.

A.5. Impact on Small Businesses or Other Small Entities

The proposed data collections do not impact small businesses or other small entities. The collections will focus on people in their roles as individuals during their personal time.

A.6. Consequence of Collecting the Information Less Frequently

FDA plans to use a variety of media messages and materials to inform and educate the public about how to safely use online pharmacies. During these first few pivotal years of the emergence of a mass market for online pharmacies, it is critical that FDA invest the time and resources into a strategic approach to communication to ensure that consumers are sufficiently informed so that they can make appropriate choices. Sound research and evaluation are needed as integral parts of initial program design rather than as afterthoughts to program implementation. With the rapidly changing nature of the Internet, and with the growing use of online pharmacies, continuing research will ensure that the appropriate audiences are targeted and that FDA is communicating with them in the most effective ways. This is critical as only through effective communications will consumers be sufficiently informed to make appropriate choices, and only then will FDA serving the public as mandated.

Communicating effectively about the use of online pharmacies to purchase prescription drugs involves conveying complex concepts. Without testing, FDA will not fully understand the concerns of consumers or whether messages are serving their intended purpose. As a result, FDA could be spending more than a million dollars on a campaign that is ineffective in achieving its intended purpose. FDA must effectively assess whether its communication messages are appropriately and understandably reaching the targeted audience and being incorporated into their belief structures and behaviors. Continued testing is needed to assess continued message relevance given dynamic social and environmental factors and the public's changing education and information needs.

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

There are no special circumstances for the collection of the information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of July 12, 2011 (76 FR 40920; Docket No. FDA-2011-N-0494). A 30-day notice for public comment was published in the FEDERAL REGISTER of October 19, 2011 (76 FR 64949). No comments were received during the specified periods.

A.9. Explanation of Any Payment or Gift to Respondents

The respondents will be drawn from online panels coordinated through eRewards, an online market research firm. Panelists are recruited through multiple sources including email and online marketing with over 300 diverse online affiliate partners. There are over 2,400,000 adults residing in the U.S. in eReward panels. This is an opt-in e-mail program. Panelists are periodically sent e-mail communications from e-Rewards inviting them to participate in surveys. Panelists receive a reward for participating related to the survey length, interest and complexity – the amount varies for each survey but is clearly stated in the invitation email (see Attachment 3).

Respondents will receive $4.00 in e-Rewards currency for the survey. e-Rewards currency does not have a dollar-for-dollar exchange, but can be leveraged for goods (magazine subscriptions, frequent traveler points, Omaha steaks, handbags, etc.) by respondents as currency accumulates in their account.

A.10. Assurance of Confidentiality Provided to Respondents

All data collection and analysis will be conducted in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements. Information provided by respondents will be kept private to the extent permitted by law.

The vendor recruiting participants and hosting the online survey posts a link to their privacy policy on every invite for an online survey, which reads as follows: read our Privacy Policy: http://www.e-rewards.com/privacypolicy.do#6. In this privacy policy, current and potential participants are informed that registration requires their full name, postcode, date of birth, e-mail address, and number of e-mails desired to be received in a week. The database uses a certified service for protecting the security of the information. Participants have the option of providing demographic profile data (like occupation, travel frequency, and areas of interest). The privacy policy also states that surveys may request information defined as sensitive (e.g. data directly or indirectly revealing racial and ethnic origins, political, philosophical or religious opinions, trade union affiliation, health or sexual life), but that they are not required to provide this information if they do not want to and failing to provide this information will not preclude them from participating in the e-Rewards program.

The introduction of the survey (see revised survey instrument document and screen shots, Attachments 4 and 5) will also advise respondents of: the nature of the activity; the purpose and use of the data collected; FDA sponsorship; and the fact that participation is always voluntary.

Only personnel from the contractor conducting the information collection will have access to individual-level survey data. All project staff from the contractor conducting the information collection will take required measures to ensure the privacy of data. All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy, all presentation of data in reports will be in aggregate form. Reports will be used only for research purposes and for the development of communication messages.

FDA's IRB, the Research Involving Human Subjects Committee, have considered this data collection to be exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(2) of 45 CFR Sec. 46.101 (Attachment 6).

A.11. Justification for Sensitive Questions

Findings from the survey will be used to target consumers at greatest risk for health risks—including those purchasing from online pharmacies based outside the United States—with educational messages for making safe purchases online. For this reason, items in the survey ask respondents whether they have made purchases in the past from foreign pharmacies or intend to do so in the future (see questions 5 and 7 on Attachment 4, Survey Instrument). Participants may perceive they run the risk of inciting legal action if they respond positively to this question. Although importing pharmaceuticals is illegal in many cases, there are conditions under which purchases for personal use are allowed. The question is therefore worded to allow for this legal possibility: "Some people order prescription medicines online from a pharmacy outside of the U.S. because they cannot get the prescription locally, or because they find it at a lower price. To the best of your knowledge, have you purchased from an online pharmacy based in a country outside the United States?" In reality, enforcement efforts target suppliers and rarely pursue individuals making purchases for personal use.

Questions on race and ethnicity may be considered sensitive; this information is collected by participants when they opt in to be part of the panel and will not be asked in the survey. All information on race/ethnicity collected by the vendor complies fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

As described in Section A.10, all respondents are assured that the information is voluntary and will be treated as private, and they have the option of not answering questions they do not want to answer.

A.12. Estimates of Annualized Burden Hours and Costs

Table A.12.1 provides an estimate of the burden incurred during each year of the three-year period. The proposed data collection methodology is described in more detail in Section B.

In proposing the sample size we took into consideration that the variance of the variable being studied in the population is virtually unknown, as well as an acceptable margin of error. We used a common "rule of thumb" for sample size calculation using percentages (or proportions) based on the following equation:

Sample size (n) = [(1.96^2 x 2500)/(Margin of error^2)]

We seek a low margin of error (1%) for baseline data on this important public health issue. A sample size of 5000 would meet the requirements for a low margin of error and would meet the needs for the proposed analyses. The analyses methods include regression and cluster analyses in order to distinguish characteristics of groups, and the sample must be a sufficient size to use these methods. Previous studies indicate about four percent of the population are at highest risk. A large sample (n=5000) of "opt-in" online panelists would yield about 200 people (4% of 5000) who are in the high-risk population. Making comparisons within the groups, for example by Gender (2 choices) x Income group (4 levels) produces 8 cells or smaller groups total, and the

analyses require at least 20 people per cell in order to be able to make stronger statistical inferences, i.e. use of a meaningful statistical test would require a minimum sample of 8x20 = 160. It is unknown what proportion may fall into populations of low or medium risk.

The time required for screening and participation will be approximately fifteen minutes per participant. Based on an expected response rate of 70 percent, we anticipate inviting around 7,140 respondents to achieve 5,000 completed responses for a total estimated respondent burden of 1,250 hours per survey.

Table A.12.1

Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey Study	5,000	1	5,000	.25 (15 min.)	1,250

Unlike surveys of establishments, which can require detailed recordkeeping to provide responses to very specific survey questions, the aim of the research is to collect attitude and opinion data from individuals. There is no annual cost to respondents to collect the information.

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

No capital or start-up costs will be incurred as a result of these information collection activities.

A.14. Annualized Cost to the Federal Government

Costs will include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, collecting and analyzing information, and reporting and disseminating findings. In the initial contract year, it is anticipated that approximately $75,000 in contractor expenses will be expended to fund at least one survey.

In addition, government staff costs may be incurred for monitoring by the government Project Officer, projected to be about 50% of an FTE's time per year (1,000 hours). Given an FDA personnel cost of $52.61 per hour, $52,610.00 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $252,610.00 (which is equal to the total of contractor expenses [$200,000] plus FDA government staff salary cost [$52,610.00]).

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The process for developing the analytical plan for this research is similar to that used in any formal evaluation. Staff reviewed the material to be pretested, discussed the objectives with the individuals responsible for developing the materials, determined the analytic questions to be addressed, and then prepared the procedures, instruments, and data analysis plan. The survey instrument that has been generated by this process is included in Attachment 4.

Techniques for analyzing data include primarily quantitative analyses including descriptive statistics, percentages, cross tabulations, and averages. These statistics will be calculated and presented, along with demographic descriptions of study respondents. Information collected from study participants will be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race/ethnicity, etc.). Inferential statistical analyses may be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; non-parametric procedures will be used otherwise. The predictive modeling will rely on logistic regression and latent class cluster analysis. All of the analyses will be done in the context of understanding the limitations of the data with respect to their lack of generalization to the general population.

FDA may present the findings of its pretest work at professional association meetings, including those of the American Public Health Association, the Society for Public Health Education, and the Drug Information Association. Some results may be published in professional journals such as the *Journal of Public Policy and Marketing* and the *American Journal of Public Health*. In any findings presented at professional association meetings or in professional journals, FDA will state the limitations of the data.

A notional schedule for this collection is shown below:

Project Time Schedule

Activity	Time Schedule
Finalize materials & programming	2 weeks after OMB approval
Pilot testing & revisions	4 weeks after OMB approval
Collection of data	6 weeks after OMB approval
Analysis of data	8 weeks after OMB approval
Report on survey	12 weeks after OMB approval

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

The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.