FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (#0910-0677)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Testing FDA's Drug Safety Communications with Consumers to Improve Consumer Knowledge about How FDA Communicates Risks and Benefits of Prescription Medicines

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Communications (OCOMM) is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Testing of FDA's Drug Safety Communications…" to test Drug Safety Communications (DSCs) to obtain consumers' knowledge, attitudes, beliefs, and behaviors related to obtaining drug safety information generally and the effectiveness of recently issued DSCs, and also to gain consumer input as to how DSCs might be improved for communicating risks and benefits of drugs to the American public.

   All drugs have risks, and health care professionals and patients must balance the risks and benefits of a drug when making decisions about whether to use it. The general risks and benefits of a drug are described in the product's prescribing information, also known as product "labeling." FDA provides information on drug risks and benefits to health care professionals and patients when a specific concern is generated. Historically, however, FDA waited until that information had been fully evaluated scientifically and had prompted a regulatory action, such as a revision to the drug's prescribing information.

   More recently, FDA is issuing DSCs as information becomes available to communicate about important drug safety issues, including emerging safety information, about marketed drugs. DSCs are standardized electronic communications posted on the FDA Web site. They are written in plain language to the extent possible, and they include the following sections:

   - A summary of the safety issue and the nature of the risk being communicated
   - The established benefit or benefits of the drug being discussed related to the safety issue at hand
   - Recommended actions for health care professionals and patients, when appropriate
   - A summary of the data reviewed or being reviewed by FDA

   FDA describes information presented in DSCs as *emerging drug safety information*. This term describes information about a drug that FDA is monitoring or analyzing that may alter the benefit–risk analysis for the drug. The potential change in benefit-risk analysis may affect decisions about prescribing, monitoring use, or taking the drug, but because the change has not yet been fully analyzed or confirmed, the new drug information is still

considered emerging. Such information may relate to new risks or new information about known risks.

FDA provides this emerging drug information in DSCs as one of the few mechanisms through which consumers and healthcare professionals can receive new information about a drug after it has been FDA approved. DSCs can provide drug warnings, can inform the public of a label change in light of newly discovered side effects, or can simply inform the public of ongoing investigations.

Some DSCs are related to drug safety issues that continue to develop as more information is obtained. FDA may disseminate a follow-up DSC (a DSC update) to keep the public informed of new information pertaining to a previously communicated DSC. In addition, some emerging safety information may take a long time to evaluate (if, for example, there is a need for additional clinical trial or epidemiological data to further assess the risk).

Given the important, sometimes lifesaving information provided by DSCs, ensuring that the public understand and use the information presented is of vital importance to improving the overall health of all U.S. citizens. Therefore, these focus groups are needed to:

- Evaluate consumers' knowledge, attitudes, beliefs, and behaviors related to obtaining drug safety information.
- Evaluate knowledge, attitudes, beliefs, and behaviors of recently issued DSCs.
- Obtain consumers' reactions and recommendations to FDA on the DSC format, language, messages, and general content.
- Help FDA assess whether consumers perceive and understand risk better when presented to them as absolute risk or whether they understand it better when presented as relative risk (or both).
- Assist FDA to better understand how and when to communicate emerging drug safety information (i.e., safety information about a drug that is reported but not yet evaluated and/or confirmed).
- Explore a systematic qualitative rating system to characterize the risk of drugs and to provide judgments of the quality of evidence and the strength of recommendations.
- Explore the value of having poison control center numbers featured on DSCs.
- Provide current data on best practices to communicate with audiences at various levels of health literacy, including those who are medically underserved or face health disparities.
- Develop a standard format and/or practices to communicate drug safety to audiences with various levels of health literacy, including those who are medically underserved or face health disparities.

This work is critical to supporting FDA's key priorities to improve the safety and effectiveness of medical products and the safety of the drug products available to consumers. This work will be used to refine the FDA Drug Safety Communications in order to better inform consumers and health care professionals. It strengthens the Agency's ability to fulfill its public health mission by educating consumers on the safety of medications, and readily recognizes and responds to emerging safety concerns and issues that arise about drugs. In addition, it assists FDA in its goal of improving understanding of the real-world health outcomes from medical products by encouraging readers to report any side effects they experience to the FDA MedWatch program.

2. **Intended use of information:**
The information collected in these focus groups will be used to identify how DSCs and other drug safety communications might be improved for communicating risks and benefits of drugs to the American public. Specifically, the information obtained through these focus groups will be used to:

- Improve communication and public understanding of the risks and benefits of prescription medicines and drug safety information
- Improve consumer understanding and use of DSCs
- Obtain feedback related to consumer reporting of risk for a given drug
- Obtain insight into understanding of drug safety information and DSCs among consumers with various health literacy levels to assist FDA more effectively communicate with consumers, including those who are medically underserved and/or face health disparities.

Information collected through the focus groups will also be used to develop a survey that will be used to quantitatively test and refine drug safety communications to better convey risks and benefits information.

3. **Description of respondents:**
FDA contracted with Ipsos U.S. Public Affairs to conduct these in-person focus groups. Respondents will be adults 18 years and older from the general U.S. population living in four different geographic regions. Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener. A minimum of 8 participants will be included in each group. Participants will be divided into groups based on their scores on a standardized health literacy measure, such that 12 groups will consist of individuals with low health literacy scores, and 12 will consist of participants having moderate health literacy scores. At least 15% of respondents in Philadelphia, Fresno, and Asheville will come from zip codes with medically underserved areas (as defined by the Health Resources and Services Administration). All respondents will have taken at least two (2) over-the-counter or prescription medicines in the last 6 months, will suffer from a chronic condition, and will use the internet for at least 2 hours a month. Respondents will not work for an advertising agency, a market research company, a communications/PR firm, a pharmaceutical company, in the healthcare industry, or as a scientist or researcher. Finally, anyone who participated in a focus group within the last three months will be excluded.

4. **Date(s) to be conducted and location(s):**
Twenty-four focus groups will be conducted in July and August 2014 in the following locations:
Philadelphia, PA
Fresno, CA
Appleton, WI
Asheville, NC

5. **How the Information is being collected:**

Recruitment Information

Ipsos will contract with focus group facilities in each of the four locations. Staff from the focus group facilities will recruit participants using the participant screener (attached) under the supervision of Ipsos. The facilities' staff will book the proper focus group participants into the low and moderate health literacy groups. The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will recruit 12 participants for each session, to ensure a minimum of 8-10 participants "show."

The focus group facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

Ipsos staff members will serve as moderators for all focus groups, which will last about 2 hours. CDER OCOMM staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology. The focus group facilities will make audio and video recordings of the group events to ensure a verbatim record of the proceedings is captured. Transcripts will be created to facilitate the moderator's reporting of the groups.

The moderators will use the attached moderator guide to ensure that all relevant topic areas are addressed.

Ipsos and the focus group facilities will comply with safeguards for ensuring that participant information is kept private to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. Number of focus groups:

24

7. Amount and justification for any proposed incentive:

Our experience in conducting focus group research indicates that offering an incentive that is below the accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following.

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group

In preparation for these focus groups, Ipsos consulted with facilities that host focus groups to determine incentive rates. The contractor informed us that proposal of lower incentives resulted in the facilities refusing to accept the job. Given this information, we

propose an incentive of $75 to ensure that we are able to attract a reasonable cross-section of general population participants.

Additionally, there is some evidence that using incentives can actually reduce nonresponse bias in some situations by bringing in a more representative set of respondents.[1] [2][3] This may be particularly effective in reducing nonresponse bias due to topic saliency.[4]

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):

No statistical methods will be used.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 2 shows the estimated annual reporting burden for the groups, assuming 9 participants per group.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
General Population	216	120*216	432

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1 Castiglioni, L., & Pforr, K. (2007). The effect of incentives in reducing non-response bias in a multi-actor survey. *Presented at the 2nd annual European Survey Research Association Conference*, Prague, Czech Republic, June, 2007.

2 Singer, E. (2002). The Use of Incentives to Reduce Nonresponse in Household Surveys. (R. M. Groves, D. A. Dillman, J. L. Eltinge, & R. J. A. Little, Eds.) *Survey nonresponse*, (051), 163 -178. University of Michigan Institute for Social Research. Retrieved from http://www.isr.umich.edu/src/smp/Electronic.

3 Singer, E. (2006). Nonresponse bias in household surveys. *Public Opinion Quarterly*, 70(5), 637-645.

4 Groves, R., Couper, M., Presser, S., Singer, E., Tourangeau, R., Acosta, G., & Nelson, L. (2006). Experiments in producing nonresponse bias. *Public Opinion Quarterly*, 70(5), 720-736.

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