FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "FOCUS GROUPS ABOUT DRUG PRODUCTS" (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: Medical Countermeasures Message Testing

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 is seeking OMB approval under the generic clearance 0910-0677 for the focus group project, "Medical Countermeasures Message Testing," to:

   - Determine the public's information priorities regarding various medical countermeasures in a public health emergency.
   - Explore the attitudes, beliefs, understanding, and behavioral intentions of members of the public with respect to draft messages relating to various medical countermeasures used during a public health emergency.
   - Prioritize the anticipated concerns of members of the public and their information needs related to medical countermeasures during a public health emergency.

   For many hazards, medical countermeasures (MCM) —medicines —represent a lifeline to an affected public. However, many of these medical countermeasures are not widely used or available. Furthermore, these medicines may carry unique or undocumented risks. For this reason, it is imperative that the FDA communicate rapidly and effectively with the public during a hazard scenario so they can understand the risks and benefits associated with the medical countermeasures.

   Using evidence-based risk communication theories and best practices, FDA's *Communicating Risks and Benefits: An Evidence-Based User's Guide*, the Centers for Disease Control and Prevention's *Crisis and Emergency Risk Communication [CDC-CERC] framework*, and Message Mapping techniques, FDA worked with ORAU to develop sample messages about various medical countermeasures that could be used to treat a variety of biological, chemical and radiological terrorism threats.

   To help ensure the quality of those messages, FDA wishes to test them with the public. Oak Ridge Associated Universities (ORAU) is to provide assistance.

2. **Intended use of information:**

CDER's Office of Communications has an active research program with funds committed for important projects. The proposed focus groups will allow us to:

- Evaluate the extent to which selected medical countermeasure messages are relevant, comprehensible, credible, and motivate desired actions.

- Expand the current understanding of the public's knowledge of terrorism threats and of medical countermeasures and identify gaps in that information.
- Determine the public's preferred sources and channels of information regarding medical countermeasures and their associated public health threats.
- Obtain insight and recommendations for developing effective medical countermeasure messages and communication initiatives for public health emergencies.

3. Description of respondents:

FDA contracted with Oak Ridge Associated Universities (ORAU) to conduct these in-person focus groups.

Focus groups will consist of 20 groups with the general public and 5 groups with racial/ethnic minorities and 5 groups with the public who have a low education. Table 1 shows the breakdown of participants. Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener. See Appendix A, Screening Instrument in the attached protocol for recruiting information on low education and racial/ethnic minorities groups.

Table 1.

	Number of Groups										Totals	
	City 1		City 2		City 3		City 4		City 5			
	Day 1	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Groups**	**Recruits**
Low education	1	⟳	1	⟳	1	⟳	1	⟳	1	⟳	5	50
Racial/ ethnic minority	1	⟳	1	⟳	1	⟳	1	⟳	1	⟳	5	50
General public	1	3	1	3	1	3	1	3	1	3	20	200
Total											30	300

4. Date(s) to be conducted and location(s):

Thirty focus groups will be conducted in five major metropolitan areas. These cities have been determined based on the Department of Homeland Security's Urban Area Security Initiative (UASI) as areas most at risk for a terrorist event, Los Angeles, CA; New York, NY; Chicago, IL; Washington, D.C/Baltimore (National Capitol Region); and Atlanta, GA. Focus groups are planned for the summer and fall of 2014.

5. How the Information is being collected:

Recruitment Information:

ORAU will be responsible for identifying and undertaking all activities associated with recruiting participants. Recruiting will be conducted through the market research facilities at which sessions are to be conducted, under the supervision of ORAU.

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 10 participants for each session, to ensure a minimum of 8 participants "show."

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

Focus Group Discussions:
Each focus group will have approximately eight participants and is expected to last about ninety minutes. Focus groups are to be conducted by a commercial market research firm, using the firm's facilities and a professional moderator who will facilitate. All sessions will be conducted in English. Participants will be screened for those comfortable conversing in English

CDER Office of Communications staff members will observe most, if not all, of the sessions remotely using streaming technology. The focus group facilities will make audio 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 moderator will use the moderator's guide to ensure that all relevant topic areas are addressed.

The Contractor will comply with safeguards for ensuring 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.

(See Appendix A for Screener and Appendix B for the Moderator's Guide in the attached protocol document for details on information collection).

6. **Number of focus groups:**
   30 Focus groups

7. **Amount and justification for any proposed incentive:**
   Our experience in conducting focus group research indicates that offering an incentive below the accepted rate will result in increased costs that exceed the amount saved with 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

Furthermore, there is evidence suggesting that using incentives can reduce nonresponse bias in some situations by securing a more representative set of respondents.[1] [2][3] This may be particularly effective in reducing nonresponse bias due to topic saliency.[4] With all of the above factors in mind, we propose the following incentives for each city: $75 for focus group participants in Los Angeles, New York, Chicago, the Baltimore/D.C. region, and Atlanta.

8. Questions of a Sensitive Nature:
NONE

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):
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 10 participants for each session, to ensure a minimum of 8 participants "show."

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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.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener for the Public (General, Racial/Ethnic Minorities and Low Education)	500	5/60	42
Focus Group	300	90/60	450

REQUESTED APPROVAL DATE: June 3, 2014

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