FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS & IN-DEPTH INTERVIEWS FOR THE FDA CDER RISK COMMUNICATIONS INITIATIVE (0910-0677)

TITLE OF INFORMATION COLLECTION: Conducting Focus Groups & In Depth Interviews to Understand Perceptions Of/Attitudes toward FDA CDER Drug Safety Communications

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   FDA is seeking OMB approval to conduct focus groups and in-depth interviews to study participants' opinions of the most important and resonant elements of Drug Safety Communications (DSCs) produced and distributed by FDA CDER.

   In 2010, the Office of Communications within CDER recognized knowledge gaps pertaining to DSC market penetration and online behavior. Additionally, questions as to brand awareness, reach, and effectiveness (i.e., to inform and or persuade) remained unanswered. To address the gap, FDA CDER began investigating DSC dissemination, diffusion and duration patterns in the online space to: 1) provide CDER with a comprehensive understanding of what happens to DSCs once they are released, 2) construct a forecasting system that will enable FDA to anticipate and identify predictors of message effectiveness and longevity, and 3) use research outcomes to inform CDERs DSC strategic communication plan.

   Thus far, CDER has conducted a retrospective analysis of 24 DSCs and their respective communications lifecycles using an online social media evaluation tool. Research has returned a wealth of information on the behavior of DSCs, and FDA now wishes to conduct focus groups and interviews to elicit the knowledge, attitudes, and beliefs about the DSC communications process and policies from FDA personnel and a lay audience external to FDA. More specifically, FDA wants to understand what information within DSCs is most important and compelling to the participants' understanding of FDA's intended messaging and communications purpose for the DSCs. Additionally, this project seeks to investigate the similarities and differences of opinion of participants on these issues to determine if core elements essential to successful DSCs can be gleaned and applied to a predictive model of core communications elements for inclusion in future DSCs.

   The focus group and interview feedback will allow FDA to assess the potential effectiveness of its messages in successfully communicating with their intended audiences. Research outcomes will help FDA assess what elements within the DSCs might be adjusted to ensure greater message dissemination, diffusion and duration.

2. **Intended use of information:**
   FDA expects to use the findings from these focus groups and interviews to inform their message construction and distribution strategies. The results of these focus groups will also help inform the FDA's newly established Risk Communication Advisory Committee and would constitute a further effort to respond to the Institute of Medicine's recommendation in its September 2006 report "The Future of Drug Safety" that FDA

improve its communications with the public. The data will not be used for the purposes of making policy or regulatory decisions.

The Contractor will provide FDA with an independent analysis of the results based on the audio/video tapes and transcripts of the groups. The raw data for these reports will be the words, phrases, sentences, and non-verbal responses of the participants. The final report will be based on the discursive data gathered from each group. The report will detail the characteristics of each group and will highlight variations and commonalities between the groups. Because focus group research constitutes a qualitative methodology, quantitative results will not be reported. FDA recognizes that the data collected will not be statistically representative of population segments characterized by the groups.

3. Description of respondents:

FDA contracted with Deloitte Consulting LLP and Global Prairie (referred to as the Deloitte Team) to conduct these in-person focus groups.

Focus Groups/Interviews with Lay Audience

For the lay audience, The Deloitte Team will construct a participant screening tool with selection criteria and work with a professional focus group facility to identify participants.

Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener.

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

Pending OMB approval by [date requested], focus groups are planned for the following dates and locations.

[Dates and Locations TBD]

5. How the Information is being collected:

<u>Recruitment Information</u>

Lay Audience Focus Groups

Staff from the focus group facilities will conduct subject recruitment using the screening tool. The facilities' staff will book the proper focus group participants into the healthcare professional and non-healthcare professional 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 9 participants "show."

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

We will contract with a professional market research firm to contact potential healthcare professional and non healthcare professionals and screen them for eligibility using a participant screener. The participant screener will include items on race and ethnicity consistent with OMB standards:

Are you of Hispanic, Latino, or Spanish origin?

Yes
No

What is your race? Please select one or more.

White
Black or African American
American Indian or Alaska Native
Asian
Native Hawaiian or other Pacific Islander

Participants for both groups will be provided a description of the project along with a statement of risks and benefits of participation during the recruiting efforts. These descriptions will be reiterated at the start of each session. Agreement to participate will be considered acceptance of informed consent, consistent with standard focus group methodology.

Focus Group Discussions

Members of the Deloitte Team will serve as moderators for all focus groups. Members of the FDA CDER will be provided the opportunity to observe the sessions from the observation rooms at the focus group facilities. For the lay audience participants, the focus group facilities will make audio recordings of the group events to ensure a verbatim record of the proceedings is captured. Additionally, at FDA's request, the focus group facilities can make video tape recordings of the sessions.

The moderator will use the attached moderator guide to ensure that all relevant topic areas are addressed. Key research questions for the project are summarized below:

- Do healthcare professionals and non-healthcare professionals pick out the same important elements within the Drug Safety Communication?
- How much convergence and/or divergence are (is) there between healthcare professionals and non-healthcare professionals in the perception of the important elements of the Drug Safety Communications?
- How much convergence and/or divergence are (is) there between the external audiences and the internal (FDA) subject matter experts (see Task 2) in the perception of the important elements of the Drug Safety Communications?

Discussion will begin on or near the prearranged time. After short introductions, the moderator will ease the participants into a discussion of specific topics with a more general "warm-up" question. The moderator will not pose any questions of a sensitive or private nature. The moderator will continue to facilitate the discussion until all of the topics in the moderator guide have been addressed. Time is allowed to address ideas and questions spontaneously generated from the discussion. Reliability and validity will be assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification. This will be done both within the course of the individual sessions and between the separate sessions. The groups will be audio and video taped. Written and electronic transcripts of the focus groups will be prepared from these tapes, with all personally identifying information removed. These transcripts will be used by the moderator to prepare a final report.

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 an individual.

6. Number of focus groups:

Lay Audience Focus Groups
Healthcare Professionals: 4 focus groups
Non-Healthcare Professionals: 4 focus groups

7. Amount and justification for any proposed incentive:
Healthcare professional group participants will be paid a $200 participation incentive; non-healthcare professional group members will be paid a $90 participation incentive. The incentive reflects the estimated value that a focus group participant places on their free time.

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

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e., Sample Size & Method of Selection):

Lay Audience Focus 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 9 participants "show."

The Contractor will recruit approximately 96 individuals, expecting to have eight or nine participants per group. No more than nine participants will participate in a group, regardless of whether or not more than nine arrive as planned. Past experience has shown that this amount of over-recruitment generally ensures that enough participants will show up for the groups.

The time required for screening and participation will be two hours per participant. There will be a total of no more than 12 participants in 8 groups, producing a conservative total estimated respondent burden of 192 hours.

BURDEN HOUR COMPUTATION *(Number of responses (96) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
General Public (healthcare professionals and non healthcare professionals)	96	120 * 96	192

REQUESTED APPROVAL DATE: TBD

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