FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

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: FDA Unified Consumer Communications Program

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration's (FDA) Office of External Affairs (OEA), proposes to conduct a series of eight (8) focus groups, one for each primary FDA target audience that has been identified for the Unified Consumer Communications (UCC) project. The purpose of the groups is to test and gather qualitative feedback on three (3) separate and distinct visual design options to select a recommended creative approach for FDA to develop into a new unified visual identity for the entire agency. The new identity will help visually brand the look and feel of the FDA while creating and implementing internal business and communication process improvements.

2. Intended use of information:

The results from the focus groups testing will be used to select a single concept to move forward with in the development of the new unified visual identity for the FDA. Each visual design option that will be tested during the focus groups shall include the following elements: logo/tagline, color palettes, typefaces/fonts, stationary, posters, e-newsletter template, and photography. This includes a list of commonly produced items identified during the development of the briefing document and in consultation with the agency to optimize the cost efficiencies created by the new unified business process.

The focus groups testing will allow for FDA to understand which concepts resonates the best with each key target group in order to eventually make a decision on the creative concept that will continue to be developed further after the testing phase.

3. Description of respondents:

FDA contracted Sensis, a communications firm, to conduct these focus groups. The groups will be held within testing facilities in four national markets. Focus group participants will be made up of four (4) groups in total. The Contractor shall complete two (2) tests with each group. Participants will be recruited from the following cities: Philadelphia, Atlanta, Los Angeles, and Chicago. The breakdown of the groups will include the following:

- Two (2) mixed groups of health professionals (general practice, family practice, internists, pediatricians, and nurse practitioners)
- Two (2) mixed groups of researchers and scientists
- Two (2) mixed groups of consumers
- Two (2) mixed groups of industry professionals (pharmaceuticals, biotechnology, blood banks, vaccine manufacturers, medical devices, food producers and manufacturers, and cosmetics and dietary supplements)

During the screening process, the Contractor shall look for participants that include the following qualifications:

- Have not participated in focus groups in the past six months

- Range in age between 25-65 years old
- Are currently employed full-time
- Consumer groups will be comprised of a mix of ethnicities and races
- Have completed at least a high school level of education
- Do not work or have any family members that work at the FDA, in media or public relations, at advertising or marketing firms, or market research firms
- Professional groups will be comprised of participants that work for a company or organization that specializes in the markets that the FDA regulates

Focus group participants will be made up of the following four groups: consumers, health professionals, scientists/researchers, and industry professionals. The participants will discuss a series of questions posed to them by a trained moderator that will ask participants to share their personal perceptions, experiences, opinions, and sources of information regarding public health and the FDA. They will be asked to respond to a series of questions concerning:

- each participant's perception of health as it applies to their profession or personal opinion
- each participant's understanding of public health entities and organizations
- words and associations that come to mind when exposed to mood boards
- understanding of participant's perceptions and attitudes towards the FDA
- preference and impressions of creative concepts that expose options of the a new unified visual identity of the FDA
- the participants insights towards the diagnostics, logo(s) and lock-up and branding, individual concept elements, and preferred creative approach.

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

The groups will be conducted in four (4) major national markets in May 2015. The exact dates and locations are listed below:

Metro Philadelphia – Marlton, NJ
9000 E. Lincoln Drive; Building Two Suite 224
Marlton NJ 08053
Date: Wednesday, May 20th

Atlanta
One Atlanta Plaza
950 E. Paces Ferry Road NE Suite 800, Atlanta GA 30326
Date: Thursday, May 21st

Los Angeles
6053 West Century Blvd Suite 100, Los Angeles CA 90045
Date: Wednesday, May 27th

Chicago
8725 W. Higgins Road Suite 150, Chicago IL 60631
Date: Thursday, May 28th

5. How the Information is being collected:

The Contractor will use a participant screener to recruit participants and facilitate a guided discussion. Participants will then be recruited to attend a focus group at one of the four market testing cities. The Contractor will provide FDA with an independent analysis of the results after the groups are completed.

Between 4-7 days before the date of a particular focus group, the Contractor will mail to recruited participants a confirmation letter signed by FDA officials and an informed consent form. This will inform participants about how the groups will be recorded and reported, and the voluntary nature of the participation. At the beginning of each group, the moderator will confirm that participants read the consent form and orally consent to participate and to have the session recorded. The recordings will be used by the Contractor to generate a written summary report of the group discussions.

The Contractor will comply with additional safeguards for ensuring participant confidentiality. The last names of the participants will not appear on any focus group materials (typed lists of participants and draft or final reports). Verbatim quotes included in the final report will not be attributed to an individual.

Discussion begins on or near the prearranged time, when most or all of the participants have arrived and are settled in the testing facility. After short introductions, the moderator eases the participants into a discussion of specific topics with more generalized "warm-up" questions that ease participants into the discussion. The moderator does not pose any questions of a sensitive or private nature. The moderator continues 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 are assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification.

Using the audio tapes and summary notes, the moderator will prepare a final interpretive report for the eight (8) groups. The raw data for this report 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 any and all significant variations and commonalities between the groups. The report will also recommend a single creative concept to move forward with in the development process of the FDA new unified visual identity.

6. Number of focus groups:

There will be a total of eight (8) focus groups in total. Two (2) focus groups will be completed in each of the four (4) testing markets.

7. Amount and justification for any proposed incentive:

The Contractor will recruit approximately sixty-four (64) individuals, expecting to have six (6) to eight (8) participants per group. No more than eight (8) participants will participate in a group. Over-recruitment is necessary to ensure that enough participants will show up for the groups.

Monetary incentives are vital to the ultimate success of the U.S. Food & Drug Administration's Unified Consumer Communications (UCC) focus group tests. The focus group tests will help FDA gather qualitative feedback on three visual design options that will lead into the development of a new unified visual identity for the entire agency. These groups are a key component to the success of this project and therefore the need exists to recruit the most qualified participants that will help drive the best results through the testing phase. The primary purpose is to incentivize our highly-skilled test group of respondents to attend the focus group. Experience has proven that unless properly incentivized, the groups the FDA is targeting tend not to appear for testing purposes. A trained moderator has been assigned to ensure the incentive does not sway people's responses.

Compensation is the main motivator for participants to agree to attend focus groups. FDA has identified four primary target audiences we will be testing in a series of eight groups, including

health professionals, researchers and scientists, industry professionals, and consumers. These groups have demanding schedules and are very protective of their free time. Incentives reflect the value a focus group participant places on their free time. Therefore, it becomes extremely difficult to recruit participants that bring real value to the project if the incentive is low. Offering low incentives may also insult potential participants.

The incentive is not a reward or salary, it is simply an incentive that serves as a stimulus to attend the session. The primary focus of the incentive is to get participants to attend and arrive on time. Due to the focus groups being conducted during a holiday season, a high enough incentive is necessary to attract participants during a period that may be used for travel. According to industry standards, offering incentives will allow us to increase the participant turnout since participants have a concrete reason for attending. Most importantly, incentives are more eager and favorably disposed toward participating in a study. Participants have a more positive attitude when they feel as though they are being compensated for their time. Incentives also allow for the recruiting period to move quicker since we are running against a very tight deadline.

At the end of the focus groups, participants will be exposed to the FDA and the new creative approaches we present. Though the moderator will not mention or expose any sensitive information about the organization or project, the participants will naturally correlate the study to the FDA. Therefore they will associate the incentive amount with the amount they believe the FDA values them. We want to avoid this at all costs.

Based on the following rationale, in order to recruit qualified participants who will bring value to the overall FDA UCC project, a need for incentives is imperative.

Participants will receive the following incentive amounts:

- Health Professionals: $100 for 1 ½ hour focus groups
- Researchers/Scientists: $100 for 1 ½ hour focus groups
- Consumers: $100 for 1 ½ hour focus groups
- Industry Professionals: $400 for 1 ½ hour focus groups

Participants will receive a confirmation letter from FDA 4-7 days prior to the scheduled session and will be contacted with a reminder phone call the day prior to the scheduled session.

8. Questions of a Sensitive Nature:

N/A

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

A trained facilitator will moderate the groups using the attached moderator guide to ensure that all relevant topic areas are addressed. The groups will be audiotaped and a written summary of the findings will be provided. The audiotape and summary notes will be used by the moderator to prepare a final report.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):* Ninety-six (96) hours in total and twenty-four (24) hours for each group.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Health Professionals	16	90 minutes	24 hours

Researchers and Scientists	16	90 minutes	24 hours
Consumers	16	90 minutes	24 hours
Industry Professionals	16	90 minutes	24 hours

REQUESTED APPROVAL DATE: April 27, 2015

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FDA CENTER: Office of External Affairs (OEA)