

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

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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:**

Consumer Knowledge Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed – Wave II: Focus Groups Exploring Consumer Reactions to Educational Concepts

### **DESCRIPTION OF THIS SPECIFIC COLLECTION**

#### **1. Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, “Consumer Knowledge Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed – Wave II: Focus Groups Exploring Consumer Reactions to Educational Concepts.” The objective of this study is to collect qualitative information from consumers, examining their reactions to educational concepts providing information on biotechnology-derived foods and feed.

FDA, in coordination with the Secretary of Agriculture, was commissioned to “provide consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products and animal feed”, henceforth referred to as “biotech foods and feed.” The education and outreach is intended to be implemented “through publication and distribution of science based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology, food products, and feed” (Consolidated Appropriations Act, 2017).

Representatives from the USDA’s Agricultural Marketing Service, the USDA’s Foreign Agricultural Service, and the USDA’s Animal and Plant Health Inspection Service; and the EPA’s Office of Pesticide Programs are included in the biotech foods and feed consumer research project as well as the biotech education initiative. These representatives are active members of the Consumer Research Workgroup and the Steering Committee, both established specifically for the purpose of this initiative. The Consumer Research Workgroup oversees the consumer research process and the Steering Committee oversees the entire education initiative. FDA will share all study instruments and reports with these representatives from USDA and EPA; the representatives will also receive an opportunity to provide input and observe all focus groups in real time.

Some evidence suggests consumers’ limited knowledge and understanding of agricultural biotechnology poses a significant barrier to them being able to make well-informed decisions about the purchase and use of these products (Wunderlich and Gatto, 2015; Wunderlich, et al, 2017; McFadden and Lusk, 2017). FDA proposes a targeted public information and education initiative to advance knowledge and understanding about biotechnology and FDA’s role in regulating human and animal biotech foods and feed prior to marketing.

The proposed focus groups outlined in this Information Collection Request (ICR) build on the Wave I focus groups that we conducted in February-March 2018. While these focus groups were exploratory in nature, the proposed focus groups outlined in this ICR primarily address the need for exploring consumers reactions to two creative themes, taglines, and the creative communication concepts that arose from the earlier focus groups. Wave II focus groups will assist FDA in selecting the type of images, colors, design styles, and messaging that appeal to consumers regarding biotechnology. Findings from this consumer research initiative will provide input into the development of educational

materials and the outreach strategy for informing and educating the American public about biotechnology-derived foods and feed.

In the literature review and Wave I focus groups, we found that consumers are most familiar with and prefer the terms “GMO” and “genetically modified” compared to less familiar terms such as “genetically engineered,” “GE-derived,” “agricultural biotechnology,” “biotechnology-derived, and bioengineered food.” The moderator’s guide (Appendix III) and the stimuli (Appendix IV and Appendix V) use the terms that are most familiar and comfortable for consumers to facilitate their comprehension and engagement.

During Wave I focus groups, FDA explored participants’ knowledge, attitudes, and beliefs related to genetically engineered foods. The findings concluded that participants: (1) have limited knowledge about genetically engineered foods, (2) are concerned about GE safety especially about potential adverse long-term health impacts of GE; and (3) would like to know more about benefits of GE foods to consumers.

These focus groups will be followed by Wave III focus groups that will explore consumers’ reactions and comprehension of draft educational materials on biotechnology. Draft materials will be developed to provide a variety of basic and advanced information on biotechnology. In Wave III, FDA plans to explore participants’ reactions to a series of materials and explore consumers’ comprehension level, the attraction to the materials, and the usability of the materials.

**2. Intended use of information:**

The consumer research will provide valuable input for both the development of educational concepts/messages and the outreach strategy for informing and educating the American public about biotech derived foods and feed.

Based on information from the literature review, Wave I focus groups, and additional input from educators and subject matter experts, the FDA’s creative team developed two themed concepts, and one will be selected for development into educational materials. These focus groups will examine adult participants’ reactions to the concepts, with an emphasis on understanding how they respond to different educational stimuli. The focus group findings will be used to further refine the concepts and develop educational materials.

**3. Description of respondents:**

The Wave II Concept Testing/Message Development research will consist of eight focus groups with adult participants who do at least half of the grocery shopping for their households; and who are at least somewhat knowledgeable and interested in issues of food and nutrition. All groups will include individuals ages 18 and over, and will include participants of diverse ages and races/ethnicities. (See Appendix I)

These groups will be segmented by education level and gender of participants; four of the group discussions will be conducted with lower educated participants, and four with higher educated participants; at the same time, four of all groups will be conducted with female and four with male participants. (See below)

**Focus Group Segmentation**

<b>Group No.</b>	<b>Location</b>	<b>Level of Education</b>	<b>Gender</b>
<b>Group 1</b>	Denver, CO	Lower	Female
<b>Group 2</b>		Higher	Male
<b>Group 3</b>	Nashville, TN	Lower	Female
<b>Group 4</b>		Higher	Male
<b>Group 5</b>	Austin, TX	Higher	Female
<b>Group 6</b>		Lower	Male
<b>Group 7</b>	Philadelphia, PA	Higher	Female
<b>Group 8</b>		Lower	Male

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

Focus groups will begin in the second half of July 2018, approximately three weeks from the date of OMB approval. The focus groups will be conducted in four locations: Denver, CO; Nashville, TN; Austin, TX; and Philadelphia, PA. The locations were selected based on the demographic diversity of the local population; the presence of a desired population, which will contribute to recruitment success; and the availability of professional focus group facilities that have a proven track record of successful recruiting. Both Denver, CO, and Nashville, TN, were selected because they are located near agricultural areas in which the population may be more familiar with farming issues (e.g., understanding the value of biotechnology for large-scale food producers, but also having concerns about food or environmental safety).

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

##### Recruitment Information

All recruitment will be conducted by a local professional focus group facility which will enable us to meet the criteria described in section 3, above. Recruitment strategies for these facilities include outreach to their proprietary databases.

In all locations, facility staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. They will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Staff at the facilities will review the informed consent form with participants (Appendix II) and have all participants sign and date one copy.

##### Focus Group Discussions

A Hager Sharp senior social science researcher will serve as a moderator for all focus groups. The moderator will use the attached moderator's guide (Appendix III) to ensure that all relevant topic areas are addressed.

Prior to beginning the discussion, the moderator will ensure that the FDA project director and other members of this initiative may observe all the sessions either from the observation rooms at the focus group facilities or remotely using streaming video technology. The streaming technology vendor will make both audio and video recordings of each group, as well as provide a near-verbatim transcript of each discussion, to ensure that participants' views and opinions are accurately captured. These transcripts will form the basis of the data analysis.

Hager Sharp and all contracted vendors (e.g., focus group facilities, streaming video vendor) will comply with safeguards for ensuring participant information is kept secure to the extent required 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:**

Eight focus groups of 8 to 10 participants will be conducted.

#### **7. Amount and justification for any proposed incentive:**

To prepare for these focus groups, we consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of \$75 to show a token of our appreciation to participants. The incentives will ensure that we are able to attract a reasonable cross section of participants who meet our screening requirements to participate in the focus groups.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly 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), and
- 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, which not only incurs additional costs, but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

Our proposed incentive amounts will help ensure that respondents honor their commitment to participate in the focus groups. Incentives are based on: (1) estimated costs related to childcare for three hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately \$48<sup>1</sup>; (2) an estimated cost for an average driving commute to and from the facility of approximately \$18<sup>2</sup>; and (3) our contractor’s and other researchers’ experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.<sup>3</sup> The proposed amounts are comparable to what has been the level of reimbursement for the target audiences in similar government-funded activities. As noted above, we expect that lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

**8. Questions of a Sensitive Nature:**

There will be no questions of a sensitive nature asked of participants.

**9. Description of Statistical Methods (i.e. Sample Size and Method of Selection):**

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I).

Sufficient recruits will be screened to achieve a target of 8-10 participants per group. To maximize participation rates, recruiters will make at least five attempts to contact each potential participant to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and email with information about the date, time, and place of the focus group before the groups convene.

**BURDEN HOUR COMPUTATION** (*Number of respondents (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	240	5	20
Adult 18+	80	120	160
Total			180

<sup>1</sup> Assumes an hourly rate of \$16 per hour for a professional babysitter

<sup>2</sup> Assumes travel by automobile; calculation derived from average annual commuting costs reported at [https://www.census.gov/hhes/commuting/files/JSM\\_Proceedings\\_paper.pdf](https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf), accessed 7/1/2016.

<sup>3</sup> See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, 16(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

**REQUESTED APPROVAL DATE:** June 22, 2018

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