Request for Approval under the "Generic Clearance for Quantitative Testing for the Development of FDA Communications" (OMB Control Number: 0910-0865)

TITLE OF INFORMATION COLLECTION: Agricultural Biotechnology Education and Outreach Initiative – Experimental Study to Test the Efficacy of Educational Materials

1. STATEMENT OF NEED

The U.S. Food and Drug Administration (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 United States Department of Agriculture's (USDA's) Agricultural Marketing Service, Foreign Agricultural Service, Animal and Plant Health Inspection Service, Office of the Chief Economist, and National Institute of Food and Agriculture; and the Environmental Protection Agency's (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 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.

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 biotech food for humans and animals. In 2018 – 2019, FDA conducted extensive formative research, including a literature review, an environmental scan, and nearly 50 focus groups across the country. The formative research found that consumers are most familiar with and prefer the term "GMO" to describe genetic food modifications. The research also found that consumers are generally not familiar with terms such as genetically engineered (GE) or bioengineered (BE) and often react negatively to those terms. Considering these findings, FDA developed consumer-facing educational materials using the term "GMO" in order to best reach consumers using language with which they are most familiar. Using unfamiliar terminology or language that consumers perceive as negative could fundamentally reduce the reach and impact of the Initiative. The term "GMO" will be used in social media and web content to draw in consumers to the initiative's website. The website will educate consumers on scientific and regulatory terms, such as genetically engineered (GE) or bioengineered (BE), to help bridge the

gap in consumer knowledge and awareness of agricultural biotechnology. This would include a discussion about the terminology used for USDA's new bioengineered food disclosure law. This approach has been vetted through the Initiative's Steering Committee, which includes Subject Matter Experts from all three agencies involved, and FDA Leadership.

FDA Center for Food Safety and Applied Nutrition (CFSAN) is seeking OMB approval under the generic clearance 0910-0865 to conduct an experimental study of educational materials, "Agricultural Biotechnology Education and Outreach Initiative – Experimental Study to Test the Efficacy of Educational Materials." The objective of this study is to collect quantitative information from consumers to evaluate the efficacy of the initiative's educational materials through a pre- and post-controlled exposure study incorporating experimental design. The study is to be completed and evaluated before the educational materials are made available to the public. The target date for this testing is December 2019 – January 2020, prior to the projected launch of the initiative in early 2020. A delay in the review of this submission may therefore consequently delay the launch of the initiative.

2. TYPE OF COLLECTION

[ ] Experiment [X] Survey

3. PARTICIPANT UNIVERSE AND SAMPLING PLAN

The study will employ a control group and an intervention group among a sample of general U.S. adults in a three-step process. The three steps include:

Step 1: Conduct a baseline online survey among 3,000 general U.S. adults. Working with fielding partner Ipsos Group, a global market research firm, we will recruit participants at random from the Ipsos online consumer panel. To facilitate segmentation of the data, we will use the demographic data that Ipsos routinely collects from all survey participants, including gender, age, race/ethnicity, education level, children in the household, marital status, and household income. We will also include attitudinal questions about organic and genetically engineered foods to facilitate segmentation by relevant attitudinal areas. The baseline questionnaire (Appendix A) will include items focused on knowledge, attitudes, and interest in specific aspects of genetic engineering, as well as purchase intent of genetically engineered food products. It is important to note that the questions measuring knowledge are specific to the consumer education materials that have been produced for the initiative (Appendix B). Before launching the survey among intervention participants, FDA will have an opportunity to test the survey in its programmed format online.

Step 2: The second step will be to divide the 3,000 U.S. adult baseline participants into a control group and an intervention group. The intervention group will receive the educational materials (Appendix B) on topics in agricultural biotechnology; the control group will *not* receive educational materials. The benefit of having control and intervention groups is that both groups will be equally primed by seeing the baseline survey, and have an equal chance of becoming information seekers and going online to look into the topic. However, because the educational materials are not yet publicly available, control participants will not have access to them. This is

intended to help determine the effect of the intervention group seeing the materials. The groups will be structured as follows:

- 1,500 participants randomly chosen for the control group
- 1,500 participants randomly chosen for the intervention group

Participants identified in the intervention group will be re-contacted following the baseline survey and will receive educational materials (Appendix B) in a survey format that will prevent downloading of the materials. The survey format will also include a series of questions to assess participants' opinions about the consumer education materials that they will have just reviewed. Participants will have access to the materials only in the survey format. They will not have access after completing the intervention survey (Step 2). Before launching the survey among participants, FDA will have an opportunity to test the survey in its programmed format online.

Step 3: After the intervention group has reviewed the materials in the survey format, we will then survey the entire sample of 3,000 again, noting intervention participants and control participants in the data files and crosstabulation files. The questionnaire will include the questions in the baseline survey (Appendix A). As in previous steps, before launching the survey, FDA will have an opportunity to test the survey in its programmed format online.

Our fielding vendor, Ipsos Group, has estimated that non-response for the follow-up survey (Step 3) could be as high as 50 percent, and that is why we are advocating a starting sample in Step 1 of 3,000. We will attempt to minimize non-response on the follow-up survey by sending reminders to those who have not responded. Ipsos will provide a $3 incentive in addition to the customary incentive of points to encourage response to the follow-up survey.

4. INCENTIVE

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?) [X] Yes [ ] No

Participants will receive points for completing the survey, which over time can be redeemed for small prizes or small amounts of cash. In addition to the customary incentive of points, Ipsos will give participants who complete the follow-up survey (Step 3) an extra $3. This incentive is expected to help increase response to the follow-up survey, as studies indicate that incentives significantly improve response rates and retention.[1] Studies also show that incentives reduce the cost per survey completed through their influence on the amount of effort that is required to achieve a completed response.[2] There is little evidence to suggest negative effects of incentives on data quality, sample composition, and response distribution.[3] For these reasons and because of

[1] See: Kulka, RA, et al. (2005). The use of monetary incentives in federal surveys on substance use and abuse. *Journal of Economic and Social Measurement*, vol. 30, no. 2-3, pp. 233-249; Singer, E and Cong Ye. (2013). The Use and Effects of Incentives in Surveys. *The ANNALS of the American Academy of Political and Social Science*, *645*(1), 112–141; Trussell, N and PJ Lavrakas. (2004). The Influence of Incremental Increases in Token Cash Incentives on Mail Survey Response: Is There an Optimal Amount?, *Public Opinion Quarterly*, Volume 68, Issue 3, Pages 349–367.

[2] Beebe, T., et al. (2005). Mail surveys resulted in more reports of substance use than telephone surveys. *Journal of Clinical Epidemiology*, Volume 58, Issue 4, Pages 421-424.

[3] Singer, E and C. Ye. (2013). The Use and Effects of Incentives in Surveys. *The ANNALS of the American Academy of Political and Social Science*, *645*(1), 112–141.

the large body of evidence supporting these findings, incentives have been supported in many OMB-approved information collection efforts.

5. DATA ANALYSIS PLAN

In the data analysis, we will assess significant differences between control and intervention groups and for intervention group participants from pre- to post-exposure to educational materials. Survey items will measure the following:

Changes in knowledge of:

- Basic definition of agricultural biotechnology
- Basic definition of bioengineered foods (BE)
- Bioengineered/genetically engineered (GE) crops available in the U.S.
- Reasons why farmers produce BE/GE crops
- Safety of BE/GE foods
- How long BE/GE foods have been available in the U.S.
- Which federal agencies regulate the safety of BE/GE foods
- How federal agencies regulate the safety of BE/GE foods

Changes in attitudes regarding:

- Importance of buying organic foods
- Safety of BE/GE foods
- Intent to purchase foods labeled organic
- Intent to purchase foods labeled non-GMO
- Intent to purchase foods labeled BE

We will prepare a report of the data using descriptive statistics, means testing, and other methods, such as correlation and logistical regression, as necessary to determine significant differences between control and intervention groups and for intervention group participants from pre- to post-exposure. No personally identifiable information of any participants will be included in the data tables, data files, or reporting. The report will include recommendations for any necessary changes to the consumer education materials to ensure they are clear, comprehensible, appealing, and relevant for consumers before they are released to the public.

6. BURDEN HOURS

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

Activity	**No. of Respondents**	**Participation Time (minutes)**	**Burden (hours)**
Screened Population	6,000	5	500
Completing Wave 1 Survey	3,000	15	750
Reviewing Educational Materials in a survey format (intervention cohort)	1,500	15	375
Completing Wave 2 (Follow-Up) Survey	1,500*	15	375
Totals	**6,000****		**2,000**

**Assumes Ipsos' estimated non-response rate of 50%*
***All participants in subsequent waves after screening are included within the 6,000 screened*

7. CERTIFICATION:

In submitting this request, I certify the following to be true:

a) The collections are voluntary;
b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
c) The collections are noncontroversial and not of a sensitive nature;
d) Personally identifiable information (PII) is collected only to the extent necessary[4] and is not retained; and
e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.[5]

REQUESTED APPROVAL DATE: December 2019.

8. NAME OF PRA ANALYST & PROGRAM CONTACT:

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[4] For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

[5] As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

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FDA CENTER: Center for Food Safety and Applied Nutrition

Attachments:

Appendix A: Survey Questionnaires
Appendix B: Educational Materials (stimuli)

- Appendix B: GMO Crops Video Storyboard
- Appendix B: GMO Timeline
- Appendix B: GMOs 101
- Appendix B: Regulatory Fact Sheet