United States Food and Drug Administration

Focus Groups as Used by the Food and Drug Administration

OMB Control No. 0910-0497

SUMMARY OF GEN ICs

Title of Collection	Participants	Use of Information	Hours Used
(CFSAN) Dietary Supplement Education Focus Groups (Formative Research) *This gen IC was originally approved by OMB on February 19, 2020. Due to the COVID-19 pandemic, FDA was able to conduct only approximately half (9 of 17) of the focus groups before the generic clearance timeframe expired on October 30, 2020. This gen IC requested approval of the remaining burden hours needed to complete this project.	640 respondents comprised of older adults (ages 55 and older) and younger adults (ages 18 to 35).	This research helped to develop consumer education and outreach materials about dietary supplements.	173
(CFSAN) Safety Alert and Outbreak Advisory Templates Testing Focus Group *This gen IC was originally approved by OMB on March 27, 2020. Due to the COVID-19 pandemic, FDA was not able to conduct the focus groups before the generic clearance timeframe expired on October 31, 2020. This gen IC requested approval under the current umbrella generic expiring November 30, 2023 and was reapproved by OMB.	300 respondents, adult individuals 18 and over segmented into groups: (1) infant formula usage (half of the participants were infant formula users/parents of young children and half were tattoo ink users and potential users); (2) education level (half of participants with some university level courses and higher and half with a community college degree and lower); and (3) device type (half of the participants read the testing messages on a laptop and half read the messages on a cell phone).	This research provided findings on how to best frame FDA/CFSAN safety alert and outbreak advisory messages, thus providing valuable feedback to stakeholders on how to further enhance messaging and communication on food and cosmetic safety issues.	133
(CFSAN) Nutrition Facts Label Education	240 respondents comprised of adult consumers ages 35	The study informed FDA about the strengths and limitations of current	104

and Outreach Initiative – Qualitative Evaluation of Educational Materials	to 50.	educational materials which helped inform revisions to the materials. The results also helped uncover specific topics that warranted additional educational focus to inform development of future FDA nutrition educational materials.	
(OC) Health Care Provider Testing Associated with the Pregnancy and Lactation Labeling Rule to Improve Health Communications Related to Lactation	113 healthcare providers who care for or counsel lactating women about prescription drugs.	Research was used to assess healthcare providers' understanding of a modified PLLR labeling approach (plain language text, quick-take summaries, and infographics) intended to facilitate use of labeling information, and to identify gaps in communication of the risk message in PLLR labeling.	238
(CFSAN) Focus Groups Exploring Consumer Reactions to Nutrition Statements on Plant Based Milk Alternatives	256 respondents, ages 18 and over, a mix of diverse races/ethnicities who do at least half of the grocery shopping for their households.	This study examined consumer reactions to several nutrition statements for PBMA proposed by FDA and continued exploring consumer understanding and expectations related to PBMA that were initially examined in the previous focus group study on PBMA conducted by FDA in 2019.	213
(CFSAN) Focus Groups with Nutrition Educators *This gen IC was originally approved by OMB August 17, 202. Due to the COVID-19 pandemic, the data collection was put on hold. FDA resubmitted this gen IC for approval under the current umbrella generic expiring November 30, 2023.	600 respondents, ages 18 and over who currently work as nutrition educators, segmented by nutrition educator type.	This study helped the agency identify gaps in current communication strategies and further assisted with formulating effective educational materials.	326
(CDER) End-User Testing Associated with the "Pregnancy and Lactation Labeling Rule" to Improve Health Communications and Prescribing Decisions in Pregnant Women – WAVE II	120 healthcare providers who care for or counsel pregnant women about prescription drugs.	Research was used to assess healthcare providers' understanding of a modified PLLR labeling approach (plain language text, quick-take summaries, and infographics) intended to facilitate use of labeling information, and to identify gaps in communication of the risk message in PLLR labeling.	360
(CFSAN) Dietary Supplement Education Focus Groups – Phase 2 (Formative Research)	960 respondents comprised of 1) older adults ages 55 to 85 and 2) younger adults ages 18 to 35 both groups with mixed genders and	Research was used to test and refine consumer education and outreach materials about dietary supplements.	310

	races/ethnicities. Within the older adult groups, half of the groups were those aged 55 to 64 years and half were aged 65 to 85 years. The older adult group segmented by education.		
(OC) Skin Lightening Products: Understanding Consumer Perspectives and Effective Educational Messages	56 consumers identifying as Asian, Black/African American, White, and Hispanic who participated in listening sessions.	Findings informed education and outreach activities. Briefings also provided to OMHHE educational partner.	56
(OC) Birth Control Options (Digital and Print Communication Focus Groups)	64 individuals ages 18 to 45 who identify as women with at least a sixth grade level of education, and were of diverse races and ethnicities located in four major metropolitan areas across the U.S. (Washington, DC, MD, VA, FL, TX and CA.	Research helped inform the content, messaging, and layout of the FDA Office of Women's Health Birth Control Chart which provides health information pertaining to women's birth control options. The input also informed the development of digital and print resources to increase awareness among women, health care providers, and the scientific community about birth control options. The findings of this internal report were reviewed by HHS and were not made public. The updates to the Birth Control Chart based on the report findings are currently under review.	8
(OC) Bridging Gaps: Recruiting African and Asian American Participants in Clinical Trials and Creating Culturally Competent Messages (Round 2)	82 focus group participants at least 18 years old, 41 Black or African American and 41 Asian.	Information and feedback obtained on the testing messages were used to create/produce video and film messages for the purpose of recruiting racial and ethnic minority populations for clinical trials.	103
(CFSAN) Online Focus Groups with Low-Income Primary Caregivers * This information collection was granted approval on February 13, 2020, under a previous study name of "Focus Groups on Childhood Obesity with Hispanic Primary Caregivers." However, the investigators sought re-approval of this individual generic	600 respondents aged 18 and over who reside within the U.S. included primary caregivers of 1 or more children between the ages of 3 and 6 years. Since children from low-income families bear a disproportionate burden of obesity prevalence, the groups will include adults living in households with a size-adjusted income that is under 200% Federal Poverty	This research contributed to the existing science knowledge foundation, which was used to inform future targeted education and outreach efforts to these populations.	295

information collection from OMB since the prior approval expired on October 31, 2020, and the study team needed to revisit and revise the study design due to the COVID-19 pandemic and its associated restrictions on in-person travel and in-person congregation.	Level (FPL). The groups will be segmented by race/ethnicity: Hispanic/Latinx; African American; Asian/Asian American; Pacific Islander/Native Hawaiian.		
(CFSAN) Front-of-Pack Focus Groups	120 participants ages 18 and over, and of mixed races/ethnicities and gender, segmented by level of nutrition motivation/ literacy/knowledge (high/low) with a quarter of the groups being comprised of individuals with some university level courses and higher and three quarters with a community college degree and lower.	The information from these focus groups were used to develop a refined set of schemes for additional consumer testing.	118
(OC) Co-creation of Digital Tools to Enhance Young Adult Minority Participation in COVID-19 Trials	316 young adults in the Southern California area.	Digital tools, including a mobile app for young adults, were created using information collected to enhance recruitment of racial and ethnic minority young adults into clinical trials.	316
(CFSAN) Consumer Knowledge and Behavior Regarding Agricultural Biotechnology and Biotechnology-Derived Food Products and Animal Feed – Wave IV; Focus Groups Exploring Consumer Reactions to Educational Materials	384 respondents from different locations across the U.S., aged 18 and over of mixed races/ethnicities who do most of the grocery shopping for their households, segmented in 4 groups: 1) African American adults who are primary food shoppers and/or cook at least three meals per week for their households, 2) Hispanic adults who are primary food shoppers and/or cook at least three meals per week for their households, 3) Young adults (i.e., ages 18–24) who are primary food shoppers and/or cook at least three meals per week for their households (we	This reserach provided valuable input for both the development of educational materials/messages and the outreach strategy for informing and educating the American public about biotech-derived foods and feed. The educational materials tested in Wave IV is a continuation and an expansion of the existing FDA education initiative and is primarily found as part of a website hosted by FDA. Moreover, FDA dedicated a section of the Website to the new USDA labeling requirements and linked to the USDA's Website for obtaining more information.	224

	recommend two to four groups with this audience), 4) General adults, segmented as in previous focus group waves — two groups with lower education level and two groups with higher education level.		
(OC) Leveraging Community Engagement and Electronic Health Record Strategies to Promote Diverse Participation in COVID-19 Clinical Trials	28 focus group respondents; including representatives from Yale Center for Clinical Investigation cultural ambassadors, and staff and clients affiliated with community-based organizations in the Greater New Haven area.	Information collected was used to explore concepts of interest and assist in the development of quantitative study, complementing other important research efforts in the agency.	50
(CFSAN) Food Safety Focus Groups on Toxic Elements in Baby Food	288 respondents comprised of adult participants who are parents or caregivers to children aged 6 to 24 months, segmented by education level, location, and social media use; half of the group discussions will be conducted with lower education participants who hold an associate degree or lower, and the other half with higher educated participants with some college or higher.	The consumer research component of the Closer to Zero Action Plan provided valuable input for both the development and assessment of educational materials/messages and the outreach strategy for informing the American parents and caregivers about toxic elements in baby food. This research also provided input on what additional information about toxic elements would increase consumers' confidence with FDA's action plan on this topic. Showing non-FDA sources of information about toxic elements to focus group participants allowed us to compare FDA's approach with the approaches from popular media and academia.	173
(OC) Advancing COVID-19 Health Equity Research	121 total respondents comprised of racial and ethnic minority community members, community leaders, and healthcare professionals living in Jacksonville, Tampa, and Tallahassee, Florida.	Research helped inform development of materials to educate racial and ethnic minority population regarding clinical trial participation after data analysis from focus group discussions.	215
(OC) Attitudes and Perceptions of People Living with Hepatitis B on Participation in Clinical Trials	22 respondents aged 18 years and older, living in the U.S., and living with hepatitis B (self-reported).	Information collected was used to assist in developing strategies to improve awareness, address barriers, and foster positive beliefs regarding hepatitis B clinical trials participation of highly	36

		impacted but under-represented participants.	
(OC) Multimorbidity and Medications: The Unheard Perspective of Older Under-Represented Racial and Ethnic Minority Adults	79 respondents comprised of community-dwelling adults over age 65 taking 5 or more medications and self-reported Asian of Chinese descent who speak either English or Mandarin.	Findings were used to inform future development of culturally competent messages and effective recruitment strategies as well as to support educational and public information programs to increasing clinical trial enrollment in older Asian adults.	119
(OC) Hispanic, Black and Pacific Islander Perspectives on COVID-19 Outreach Strategies and Patient Centered Outcomes (HeAR US)	This collection has not yet been completed.	---	---
(CDER) Teratogenic Risk Impact and Mitigation (TRIM): An Evidence-based Decision Framework	30 respondents comprised of multidisciplinary expert panel participants, including clinicians, researchers, and regulators with extensive knowledge of REMS, drug risk-benefit assessments, clinical aspects of drug use during pregnancy, and prevention of prenatal exposure.	This research provided expert input to develop TRIM, a tool that considers explicit criteria to help prioritize drugs that may require a Risk Evaluation and Mitigation Strategy (REMS).	90
(CFSAN) Fish Focus Groups with those who are Pregnant, Breastfeeding, and Parents of Young Children	192 respondents aged 18 and older, a mix of race/ethnicities and genders who have eaten fish in the past twelve months. Groups segmented by 1) education level with half of the groups being comprised of individuals with some university level courses and higher and half with a community college degree and lower and 2) half of the groups will be with those who are either pregnant or breastfeeding and the other half will be with parents or caregivers of young children (6 months to <12 years old).	This study to explored consumers' understanding of the benefits and risks of fish consumption. FDA used the knowledge gained as input to explore possible ways to make FDA/EPA advice about fish consumption easier for the target audience to follow. FDA tested its existing fish advice materials to ensure that they provided consumers with useful and actionable information to make informed choices when it comes to the types of fish that are nutritious and lower in mercury.	148
(OC) Bridging Gaps: Recruiting Asian and Black/African American Participants	134 respondents aged 18 and older comprised of 66 Black or African American and 68 Asian.	Information and feedback collected were used to develop culturally competent messages for testing with Round 2 focus groups for the purpose	148

for COVID-19 Clinical Trials and Creating Culturally Competent Messages (Round 1)		of recruiting racial and ethnic minority populations for clinical trials.	
(CFSAN) Focus Groups on Consumer Perceptions of Genetically Engineered Salmon	360 English speaking respondents aged 18 and older, a mix of diverse races/ethnicities and education who consume salmon. Segmented by sex and participants' resident location; half of the group discussions will be conducted with female, and the other half with male participants.	This research provided valuable input to CFSAN to understand motivations and behaviors of salmon consumers in the U.S. This provided FDA with a baseline knowledge of consumers' motivations and attitudes towards GE salmon to help the Agency determine if any future consumer education and outreach was needed.	173
(CDER) Provider Decision-Making About Pain Management and Opioid Prescribing Focus Group	28 healthcare providers with opioid analgesic prescribing authority from Mayo Clinic and YNHHS practice.	This research was conducted in order to confirm themes identified during previously collected in-depth interview with opioid analgesic prescribers. Information gleaned from both qualitative study components were used to develop a survey instrument that will be pilot tested among a large sample of prescribers.	30
(CDER) Teratogenic Risk Impact Mitigation (TRIM): An Evidence-based Decision Framework Follow-Up	This collection has not yet been completed.	---	---
(OC) The Shades of Beauty: Understanding African American and Asian American Women's Perception and Use of Skin Lightening Products and the Potential Health Risks	64 women respondents aged 18 years and older took part in a total of 10 focus group discussions comprised of 30 Blacks or African Americans and 34 Asians.	This research utilized focus group discussions to gain insight into Black or African American and Asian women's perceptions of the use of over-the-counter skin lightening products.	82
(CFSAN) Front-of-Package Nutrition Labeling Focus Groups 2	This collection has not yet been completed.	---	---