United States Food and Drug Administration

Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control No. 0910-0891

SUMMARY OF GEN ICs 2023-2026

Title of Collection	Participants	Use of Information	Hours Used
Dietary Supplement Claims One-on-one In-depth Interview Study	These one-on-one interviews screened 2,062 respondents to seat 62 in depth interview participants. Participants were segmented by age (40-65 years old vs 66 years or older) and education (those with vs without a college education). Participants reflected a mixture of other demographics. The study focused on adults of 40+ years old who were more likely to use dietary supplements or to have chronic health conditions that trigger interest toward the use of dietary supplements.	The information helped FDA to formulate, expand, and improve educational and outreach initiatives to consumers understand the meaning and limitations of structure-function claims and promote and protect the public's health by ensuring consumers understand the information on dietary supplement products to make informed choices.	245 hours were used to screen potential participants and conduct one-on-one in-depth interview studies regarding dietary supplements.

In-depth Interviews with Healthcare Professionals and Health Educators on Environmental Contaminants in Food for Young Children	80 total respondents were screened to select 27 participants of in-depth interviews with English-speaking U.S. healthcare providers and nutrition educators whose patients and clients were parents or caregivers of young children.	The findings from these interviews supported FDA's Closer to Zero Initiative. These resources enabled healthcare professionals and nutrition educators to communicate with parents and caregivers on how to protect their young children at various ages from the effects of environmental contaminants in foods and conveyed the steps the agency is taking to ensure the safety of the food supply.	41 hours were used to conduct screening and individual in-depth interviews.
Pediatric Healthcare Provider Interviews on Bioactives in Infant Formula – Phase 2	84 respondents were screened to seat 20 interview participants, who were healthcare providers doing clinical work with infants. Interviews were segmented by type of pediatric healthcare provider (i.e., pediatricians, nurses/nurse practitioners, neonatologists, pediatric hospitalists) and setting (inpatient vs. outpatient).	The information assisted FDA in creating and disseminating effective messaging and education to help healthcare providers and consumers understand the meaning and limitations of bioactive claims in infant formula.	43 hours were used to conduct screening and in-depth, one-on-one interviews.

Food Safety Materials on Uncooked Flour	168 respondents were screened to obtain 48 focus group participants. Eight (8) online focus groups composed of adult (18+ years old) consumer primary food shoppers and who cook or bake using flour at least one time per month on average, or those who cook or bake with flour at all during fall/winter months, including October through February.	Insights from the focus groups were used to refine existing consumer educational materials as well as develop additional materials about risks posed by consuming uncooked flour. Specifically, dissemination of consumer educational materials were tested for clarity, relevance, visual appeal, usefulness, and other factors that have aided FDA in improving the effectiveness of the educational materials.	120 hours were used to conduct eight (8) online focus groups with consumers.
(HFP) Herbal/Botanical Supplement Conditions of Use Labeling Statements One-on- One In-depth Interview Study	A total of 5,000 potential respondents were screened to seat 60 participants, who were non-institutionalized US adults (18 years of age or older) who have used one or more of 20 herbal/botanical supplement products in the past 24 months. The supplements were selected because they are among the most commonly used in the US.	Data collected from this study added to FDA's scientific foundation to help the Agency better understand consumer behavior related to the use of dietary supplement labels. The data from these interviews provided baseline information to help FDA explore initiatives and approaches to promote and protect health of herbal supplement users.	490 hours were used to screen and conduct in-depth interviews.

(HFP) 2024 Plant-based Milk Alternative Focus Group Study	3,000 respondents were screened to obtain 80 participants for this focus group study across 12 focus groups. Segments: (1) 18–30-year-olds, (2) women 60+ years old, and (3) parents of children under 18 years old. Eligible respondents must also have consumed at least one type of plant-based milk alternative product (e.g., almond milk, oat milk, rice milk, etc.) in the past 12 months.	The results of the study helped inform the recommendations of the final guidance. Additionally, the results helped us develop any future steps and strategies that are pertinent and helpful in providing consumers nutrient content information of PBMA that is deemed important to public health.	A total of 304 hours were used in this collection to screen respondents and participate in the focus group.

(HFP) 2025 Allergen Advisory Statements Focus Groups	This collection screened 700 respondents seat 144 actual participants across 24 focus groups. Participants were one of the primary household shoppers. Segments: 1) Consumers with a doctor-diagnosed food allergy; 2) Parents or caregivers to a dependent with a doctor-diagnosed food allergy who is living in the household; 3) Consumers who have used epinephrine auto injectors or needed an inpatient hospital stay due to a food allergy reaction within the last five years.	The results of the study helped inform the recommendations for a potential future FDA guidance on this topic intended to improve the uniformity of allergen statements in the U.S. and reduce confusion among consumers, manufacturers, and healthcare professionals. It also helped FDA develop future pertinent steps and strategies that are helpful in providing consumers with allergen information deemed important to public health.	A total of 358 hours were used in these focus groups to conduct pre-screeners, phone screeners, email confirmations, obtain consent, send email reminders, and participate in the focus group discussion.

E-Commerce Food Labeling Focus Groups	This collection screened 192 people to seat 96 participants for 12 focus groups. Eligible participants were individuals who made the majority of grocery purchase decisions for their household and shop for groceries online at least some of the time. Segments: (1) whether they or someone in their household had a food allergy to at least one of the nine major allergens (allergen status), (2) by education.	The study findings provided additional insight about consumer needs and behaviors when shopping for food online and helped improve the accuracy of food label information across online grocery platforms. The findings of this study helped FDA improve consumers' ability to find nutritional, allergen, and ingredient information, improve their understanding of nutrition information to better compare information about food products, and reduce risks to consumers with food allergies when using online grocery platforms.	A total of 200 hours were used in screening and conducting these focus groups.
Total Hours Actually Used for ICs under Currently Approved ICR			1,801