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

Title of Collection	Participants	Use of Information	Hours Used
Focus Groups on Bioactives in Infant Formula – Phase 1	960 respondents who are U.S. adults who made the primary decisions regarding which infant formula to purchase for their household. The groups excluded those who worked or had immediate family members who worked in healthcare or public health, market research, or for food related government agencies and the groups were segmented by time zone (Eastern, Pacific, and Central-Mountain), education (lower education, higher education), and primary language spoken at home and race/ethnicity (English, all races/ethnicities; Spanish, Hispanics).	This study was part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. This research was used to highlight or identify gaps in current communication strategies and assisted CFSAN in formulating effective educational materials for bioactives in infant formula. The focus group study collected qualitative information to help FDA better understand consumer perceptions of bioactives in infant formula and had two phases planned. This phase (Phase 1) collected formative research to explore consumer attitudes, behavior, and motivations about bioactives in infant formula. The future Phase 2 will further build on what is learned in Phase 1.	280 hours were used to conduct the focus groups on Bioactives in Infant Formula

Focus Groups on Health Communications with U.S. Women	900 respondents consisting of U.S. adults who make the primary decisions regarding which infant formula to purchase for their household. The focus groups excluded those who worked or had immediate family members who work in healthcare or public health, market research, or for food related government agencies. The groups were segmented by time zone (Eastern, Pacific, and Central-Mountain), education (lower education, higher education), and primary language spoken at home and race/ethnicity (English, all races/ethnicities; Spanish, Hispanics).	The focus groups collected qualitative information to help FDA better understand women aged 45 and older consumer behaviors and motivations on obtaining nutrition and cosmetics-related information. This research was used to highlight or identify gaps in current communication strategies for older women and assist with formulating effective educational materials. Because older women have rarely been the focus of consumer outreach and research, this study aims to address CFSAN's gap in knowledge about older women's purchasing habits and will inform current and future targeted education efforts for this population.	575 hours were used to conduct focus groups discussing health communications with U.S. Women.

Cannabidiol (CBD) Interviews (Formative Research)	100 respondents who have been winnowed down to 30 interviews of English-speaking U.S. adults who were at least 18 years old and either used CBD products themselves or administered it to their pets at least 2 to 3 times a month in the past 3 months. The interviews were segmented by CBD product type and age and represented a mix of gender, race/ethnicity, and education levels.	This study was part of the agency's continuing effort to help consumers make informed choices about CBD use and aligned with FDA/CFSAN's strategic outcome to increase knowledge of consumer awareness, perceptions, understanding, and behaviors. This effort supported the work of FDA's Cannabis Products Committee (CPC)—a cross-center collective of subject matter experts to develop and implement informed strategies for protecting the health of consumers of FDA-regulated cannabis products. CFSAN collected this information because many of the product categories in the study fell under CFSAN's jurisdiction. This research was also used to highlight or identify gaps in agency understanding of consumer CBD use and has assisted CFSAN in the formulation of effective educational materials. This collection marked FDA's first qualitative data collection on consumer CBD use. FDA collected qualitative information with users based on varied product categories and FDA, through its contractor, conducted one-on-one, in-depth interviews for better understanding of adult consumers' attitudes, beliefs, feelings, and motivations related to CBD, and their reported use of products containing CBD, including foods, supplements for humans and pets, cosmetics, and vaping. FDA learned during the interviews about the sources consumers use to obtain information about CBD products, who are considered to be credible messengers about CBD, and any resistance messengers have encountered when communicating information about CBD. These interviews also explored consumer awareness of, perceptions about, and actual experiences with adverse events resulting from CBD use.	81 hours were used to conduct in-depth interviews of CBD users to help FDA in its understanding of CBD use.

CFSAN Adverse Event Reporting System (CAERS) Healthcare Provider (HCP) In-Depth Interviews (Formative Research)	45 respondents were used for this study who were English-speaking U.S. adult healthcare providers who had a patient with an adverse event or product problem from a food, dietary supplement, cosmetic, or infant formula in the past 12 months. 45 providers were screened down to 15 individual interviews which were segmented by healthcare provider type: physicians (primary care and specialists), pharmacists, and other healthcare providers, including physician assistants, nurses, and nurse practitioners, and other staff. The participants were a mix of age, level of education, race/ethnicity, and gender.	The CFSAN Adverse Event Reporting System (CAERS) is a surveillance system that collects adverse event reports (AERs) and product complaints (PCs) regarding FDA-regulated products that fall under CFSAN jurisdiction (i.e., foods, cosmetics, infant formula, and dietary supplements). AERs and PCs received on these products provide CFSAN another venue through which to monitor product safety and help serve as 'signals' to potential products of concern. In addition, CAERS receives AERs and PCs from industry, consumers, and healthcare professionals, and a recent review of the classification of CAERS reporters found that healthcare professionals are severely underrepresented relative to other types of CAERS reporters. CAERS reports are important role in helping FDA quickly identify products that may have caused AEs or PCs and act in a timely manner. FDA is looking to create education and outreach materials to increase healthcare professional reporting of AEs or PCs to FDA, and the information collected by this GenIC submission helped identify gaps in agency understanding of healthcare professionals' knowledge of CAERS and assisted CFSAN in creating effective educational materials. CFSAN, through its contractor, conducted one-on-one, in-depth interviews to understand healthcare professionals' knowledge, attitudes, and behaviors with adverse event and product problem reporting to the FDA. Healthcare professionals' experiences with treating patients who have experienced adverse events or product problems from food, dietary supplements, infant formula, or cosmetics, and their awareness of FDA CAERS reporting, including any barriers or facilitators to reporting these events or product problems were identified, and helped CFSAN learn more about the	29 hours were used to conduct in-depth interviews of healthcare professionals who have used CFSAN's CAERS adverse event reporting system..

Total Hours Actually Used for ICs under Currently Approved ICR			**965**