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 communic ations with U.S. Women. |
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| Cannabidiol (CBD) | 100 respondents who have | This study was part of the agency's | 81 hours |
|-----------------------|--|---|--------------------|
| Interviews (Formative | been winnowed down to 30 | continuing effort to help consumers | were used |
| Research) | interviews of English- | make informed choices about CBD use | to conduct |
| | speaking U.S. adults who | and aligned with FDA/CFSAN's | in-depth |
| | were at least 18 years old | strategic outcome to increase knowledge | interviews |
| | and either used CBD | of consumer awareness, perceptions, | of CBD |
| | products themselves or | understanding, and behaviors. This | users to |
| | administered it to their pets at least 2 to 3 times a month | effort supported the work of FDA's | help FDA in its |
| | in the past 3 months. The | Cannabis Products Committee (CPC)—a cross-center collective of subject matter | understan |
| | interviews were segmented | experts to develop and implement | ding of |
| | by CBD product type and | informed strategies for protecting the | CBD use. |
| | age and represented a mix of | health of consumers of FDA-regulated | |
| | gender, race/ethnicity, and | cannabis products. CFSAN collected | |
| | education levels. | 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. | |

| Reporting System (CAERS) Healthcare Provider (HCP) In-Depth Interviews (Formative Research)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: physician (primary care and specialists), pharmacists, and other healthcare providers, including physician assistants, nurses, and murse practitioners, and other staff. The participater were a mix of age, level of education, race/ethnicity, and gender.System (CAERS) is a surveillance system that collects adverse event system that collects adverse reserved down to 15 individual interviews which were segmented by healthcare providers were screened down to 16 individual motior product safety and help serve as 'signals' to potential products of concern. In addition,System.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 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 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< | | | [| |
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| Provider (HCP) In-Depth Interviews (Formative Research)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 providers type: physician and other healthcare providers, including physician assistants, nurses, and other staff. The participants were a mix of age, level of education, race/ethnicity, and gender.reports (AERs) and product complaints (PCS) regarding FDA-regulated products (Fods, cosmetics, infant formula, and dietary supplements). AERs and PCS signals' to potential products of concern. In addition,in-dept interview cares adverse eventCAERS receives AERs and PCS from industry, consumers, and 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.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 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 | | 5 | | were used |
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| or product problems were identified, and helped CFSAN learn more about the | | | | |

| Total Hours Actually | | 965 |
|----------------------|--|-----|
| Used for ICs under | | |
| Currently Approved | | |
| ICR | | |