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 Number 0910-0891
Gen IC Request for Approval

Qualitative methods generally yield data that are not statistically generalizable. As such, they are useful for testing and refining ideas, and for developing hypotheses that can be further explored using quantitative methods, which is the preferred method for informing important policy and resource allocation decisions.

Title of Gen IC: Dietary Supplement Claims One-on-one In-depth Interview Study

1. Type of Collection

   For this Gen IC FDA will conduct in-depth, one-on-one interviews.

2. Statement of Need

   This data collection will collect qualitative information on consumer perception of and reactions to labeling statements on dietary supplement products and relationships between personal background and other factors, and label perception and reaction. Dietary supplements are products intended for ingestion and to supplement the diet, such as vitamins and minerals, herbs and other botanicals, and amino acids. The Final Rule entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body" (65 FR 1000, January 6, 2000) established criteria for distinguishing between two types of labeling statements. First, "structure/function" (s/f) claims are about the effects of a product on the structure or function of the body (e.g., "Promotes healthy blood glucose level"); s/f claims may be made without prior FDA review or approval. Second, "disease claims" claiming, expressly or by implication, that a product treats, prevents, cures, diagnoses, or mitigates a disease (e.g., "Helps regulate blood sugar level"); disease claims generally require review under the drug provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

   Existing research suggests consumers in general lack understanding of differences between various types of labeling claim on food products.[1][2] We suspect the same may apply to claims on dietary supplement products, i.e., the regulatory distinction between s/f claims and disease claims may not be obvious to ordinary consumers, particularly dietary supplement users. Among other things, confusing s/f claims for having implied disease functions may cause dietary supplement users to delay or forgo FDA-approved therapies for prevention or treatment of serious diseases without any assurance that the dietary supplement will be safe and effective against the disease. Therefore, FDA desires to have better understanding of how consumers interpret s/f claims, which are displayed on many dietary supplement products, to formulate, expand, and improve educational and outreach initiatives (e.g., consumer education materials on FDA website[3]) that may help consumers understand the meaning and limitations of s/f claims. Due to resource limitations, this study will focus on s/f claims related to two chronic illnesses – diabetes and hypertension.

[1] Lin, C. T. J. (2008). How do consumers interpret health messages on food labels? Nutrition Today, 43(6), 267-272.
[2] Williams, P. (2005). Consumer understanding and use of health claims for foods. Nutrition reviews, 63(7), 256-264.
[3] For example, https://www.fda.gov/news-events/press-announcements/fda-launches-new-dietary-supplement-education-initiative-consumers-educators-and-healthcare.

3. Intended Use of the Information

The information can be helpful for FDA to formulate, expand, and improve educational and outreach initiatives that may help consumers understand the meaning and limitations of s/f claims and to promote and protect the public's health by ensuring consumers understand the information on dietary supplement products to make informed choices. This data collection is not part of a larger study or effort.

4. Description of Respondents

The target respondents will be diverse in age (40-65 years old vs 66 years or older), education (with vs. without a college education), race/ethnicity (non-Hispanic white vs. other), and gender (male, female, or non-binary). The study will focus on adults of 40+ years old because they are more likely to use dietary supplements[4] or to have chronic health conditions[5] that may trigger interest toward or use of dietary supplements.

The target number of respondents is sixty-two (62), including two pre-testers of the protocol. The remaining sixty (60) respondents will be segmented into the following three clusters to obtain a range of responses from various types of individuals.

Cluster	**User status***	**Purpose of use****	**Time zone**	**Number of interviews**
N/A	(Mock interview #1) Non-user	Not applicable	TBD	1
N/A	(Mock interview #2) User	Non-specified	TBD	1
1	Non-users	Not applicable	All 3 zones	20
2	Users	For one or more of the listed health condition(s)	All 3 zones	20
3	Users	NOT for any of the listed health conditions	All 3 zones	20
Total				**62**

* "User" is defined as an individual who has used one or more dietary supplements in the twelve (12) months prior to the date of recruitment.
** Purpose of use: Whether any supplements are used for one or more of the following health conditions: high blood pressure/hypertension, high blood sugar/diabetes, high cholesterol, cardiovascular diseases/heart disease/stroke, and cancer.

[4] Mishra, S., Stierman, B., Gahche, J. J., & Potischman, N. (2021). Dietary supplement use among adults: United States, 2017–2018. Centers for Disease Control and Prevention, NCHS Data Brief No. 399.
[5] Boersma, P., Black, L.I., & Ward, B.W. (2020). Prevalence of Multiple Chronic Conditions Among US Adults, 2018. Preventing Chronic Disease, 17:200130.

5. How the Information is Collected

Under supervision of the primary data collection contractor, Westat, staff from the recruitment facilities, as Westat's subcontractors, will recruit participants via telephone using the participant screener (Attachment 1). The recruiting facilities will use their existing databases to find prospective participants. The facilities' staff will provide all necessary information and instructions in the confirmation letter to ensure participants log in to the online platform for interviews on the agreed upon date and time (Attachment 2). Facilities will conduct recruitment and ensure that the needed number of participants are present for their scheduled time slot. The facilities will email a confirmation letter (Attachment 2), reminder letter (Attachment 3), and consent form (Attachment 4) to recruited participants for completion prior to the survey.

Westat's staff members will serve as interviewers for all interviews. FDA staff members will observe most, if not all, of the sessions remotely using streaming technology.

The interviewers will use the interview guide (Attachment 5) and a set of mock labels and mock claims (Attachments 7), with the aid of Attachment 6 (structure of the interview), to ensure that all relevant topic areas are addressed, e.g., participants' background information related to dietary supplements, their interpretation of various claims they see on product packages, and their ability to distinguish between s/f claims and disease claims. The information will be elicited when participants view various mock product labels (Attachment 7) and report how they interpret the labels and why, and when they sort claims into groups according to the differences they perceive between the claims (Attachment 7). Westat will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

6. Confidentiality of Respondents

In preparing this submission, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR will collect personally identifiable information (PII). The PII collected consists of name, contact information, age, race, gender, health information, and biometric identifiers in the form of video recordings of participant interviews. PII is collected on behalf of the FDA by a contractor or vendor who conducts surveys. PII is collected to gather information on consumer perception of and reactions to labeling statements on dietary supplement products and relationships between personal and background and other factors and label perception and reaction. Information collected by the vendor or contractor will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after the study or interview has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. All information collected will be kept secure by the vendor or contractor. FDA and any vendor or contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors or vendors maintaining information will destroy it in accordance with applicable records retention and other requirements per contract terms after the aggregate information has been provided to FDA and the survey has been completed. In keeping with IRB/Human Subjects Research protocols, the FDA clearance process ensures that study data is appropriately secured (e.g., housed on the Contractor's servers, password protected, separate storage areas for each study, access controlled).

FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

Westat will comply with safeguards for ensuring respondent information is kept secure to the extent permitted by law. The last names of the respondents will not appear on any interview materials. Verbatim quotes included in the final report will not be attributed to any individual.

7. Amount and Justification for Proposed Incentive

We propose to offer an incentive of $60 as one component in a two-pronged approach to encouraging participation and increasing recruiting efficiency.

The incentive is to compensate for the cost a respondent is expected to commit to this study. The $60 reflects the sum of (1) $42 for the 75 minutes spent on the study - the Bureau of Labor Statistics (BLS) data show the national average hourly wage of employees on private nonfarm payrolls in June 2023 is $33.60,[6] and (2) $18 for childcare during the 75-minute interview - the BLS data show the national median hourly wage of childcare workers in May 2022 is $14.22.[7]

In addition to the incentive, we also propose to appeal to altruistic motives as the second component of a two-pronged approach to encouraging participation and increasing recruiting efficiency.[8] We will state in the recruitment screener that "[T]he interviews are conducted to help FDA gather information from consumers like you to provide accurate and useful product labels to help you make informed choices about food products."

8. Questions of a Sensitive Nature

There will be no questions of a sensitive nature asked of respondents.

9. Description of Statistical Methods

Not applicable. Per Supporting Statement Part B of the Gen IC, in-depth one-on-one interviews "are qualitative research methodologies, statistical methods will not be employed to develop samples or to analyze the data."

[6] https://www.bls.gov/news.release/empsit.t19.htm, Table B-3.
[7] https://www.bls.gov/oes/current/oes399011.htm, "National estimates for Childcare Workers" under "39-9011 Childcare Workers."
[8] American Association for Public Opinion Research Task Force on Survey Refusals. (2014). Current Knowledge and Considerations Regarding Survey Refusals. https://aapor.org/wp-content/uploads/2022/11/RefusalTF_FINAL090814.pdf

10. Burden

We estimate that participants selected for this study will spend approximately 75 minutes of their time on this task, which includes time for responding to the confirmation letter (1 minute), reminder (1 minute) and consent (3 minutes), the time involved in logging in early to confirm the technology is operating correctly (10 minutes), and time to participate in the interview (60 minutes). The number of estimated screening is based on the contractor's recent recruiting experience.

Activity	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Individual In-Depth Interview Screening	2,000	5	167
Individual In-Depth Interviews	62	75	78
TOTALS	2,000	-	245

11. Date(s) to be Conducted

Starting from four weeks after OMB clearance.

12. Requested Approval Date

October 23, 2023

13. FDA Contacts

Program Office Contact	FDA PRA Contact
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