United States Food and Drug Administration
Generic Clearance: Collections for Quick Turnaround Testing of Communication Effectiveness (CFSAN)
OMB Control Number 0910-0876
Gen IC Request for Approval

The Food and Drug Administration (FDA) sometimes needs to communicate with U.S. consumers and other stakeholders about issues of immediate and important public health significance such as foodborne illness outbreaks, food recalls, or other situations requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. To better protect the public health, the agency needs quick turn-around information collected from consumers and other stakeholders to help ensure its messaging has reached the target audience, has been understood and, if needed, to update its communications during these events. This quick-turnaround generic collection gathers quantitative and qualitative information (i.e., surveys, focus groups, and in-depth interviews) to test communications or educational messages when there is an urgent public health need, assists FDA to communicate effectively about topics of public health and safety, and conveys sometimes complex concepts.

Title of Gen IC: Quick Turnaround Testing of Communication Effectiveness - Survey on 2023 Hepatitis A Virus Infections/Frozen Strawberry Recall

1. Statement of Need

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is seeking OMB approval (within 5 days) under the generic clearance 0910-0876, for the survey instrument "Quick Turnaround Testing of Communication Effectiveness Survey – 2023 Hepatitis A Virus Infections/Frozen Strawberry Recall" (Appendix I).

On March 13th, Centers for Disease Control and Prevention (CDC) issued a press release on the outbreak of hepatitis A virus infections linked to frozen strawberries[1]. On March 17th, FDA issued an outbreak advisory on the investigation of hepatitis A virus infections related to frozen strawberries[2]. Frozen strawberries sold at Trader Joe's (nationwide) and frozen strawberries sold at Costco, Aldi, KeHE, Vital Choice Seafood, and PCC Community Markets (in specific states) have been recalled, due to possible health risk related to hepatitis A virus infections.

FDA, in collaboration with CDC, has developed a survey questionnaire (Appendix I) to collect timely information on consumer awareness, knowledge, and behavior of this outbreak and recall.

2. Intended Use of the Information

The results of this survey will be used to inform both FDA and CDC's ongoing communication of this outbreak and recall with the public. Given the outbreak/recall is still ongoing and evolving, FDA and CDC may have to update communication messages based on the survey findings. Therefore, it is crucial to have this survey fielded as soon as possible to protect public health.

Data collected from the survey will be weighted to reflect the socio-demographic characteristics of U.S. adults. The Contractor (Westat) will run analyses on the data, which include frequencies, crosstabs/Chi-square test, multivariate logistic regression, and qualitative analysis (for open-ended questions).

[1] https://www.cdc.gov/hepatitis/outbreaks/2023/hav-contaminated-food/index.htm
[2] https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-virus-infections-frozen-strawberries-february-2023

The results of this survey will be used to inform both FDA and CDC's communication with the public on this case.

3. Description of Respondents

The sample size for the survey is 1,200 respondents. Respondents will be adults (18+), U.S. general consumers, balanced to the US population on age, race, and gender.

4. How the Information is Collected

The survey questions are selected from a pre-tested question bank that FDA developed. FDA has tested and refined the questions contained in the question bank with a set of nine cognitive interviews and a pre-test with 51 FDA employees. FDA and Centers for Disease Control and Prevention (CDC) worked collaboratively on selecting the questions and developing the survey questionnaire, to ensure the information collected can be useful to both agencies.

The survey will be completed online with participants recruited from an online non-probability consumer panel (Dynata). Dynata is the world's largest first-party data and insights platform that connects brands and agencies to consumers. Dynata has over 31 million panel participants in North and South America. Their members represent a broad range of ages, genders, race/ethnicities, education levels, and income.

Dynata will post invitations on their app and/or websites (Appendix II), with a link to the survey introduction and screener. If a panel participant clicks on the link, he/she will be directed to the survey introduction and screener (Appendix III). Once the panel participant finishes the screener and meets all of the criteria, he/she will be provided with a link to the programmed survey, where he/she can fill out online.

The survey will be anonymous, no personal identifiable information (PII) will be collected. Westat will receive survey data in aggregated form from Dynata. Westat will clean and run analyses on the data (see 2.). Westat will send the cleaned data set and the statistical analyses results to FDA. The data will be stored on password protected computers.

5. Privacy of Respondents and Protection of Data

In preparing this individual GenIC Privacy Act Assessment, 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 typically consists of name and contact information. PII is collected by a contractor or vendor who conducts surveys and connects brands and agencies to consumers. PII is collected so FDA can conduct a survey in collaboration with the CDC to collect information on consumer awareness, knowledge, and behavior of a current outbreak of Hepatitis A infections and frozen strawberry recall. 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.

Have you ensured that the following language or similar is included in your study materials? [include cleared language] [X] YES [ ] NO

"Your participation / nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law."

6. Amount and Justification for Proposed Incentive

Following completion of the survey, participants will receive reward points to the participant's online Dynata account that can be used in exchange for gift cards, prizes, or airline or hotel miles. For this study and population, those points correspond to approximately $3 cash value. The incentive is an effective method of drawing attention to the study and gaining cooperation for completing it. It is intended as a token of appreciation for the participants and to increase response rates.

7. Questions of a Sensitive Nature

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

8. Description of Statistical Methods

The Contractor (Westat) will run analyses on the data, which include frequencies, crosstabs/Chi-square test, multivariate logistic regression, and qualitative analysis (for open-ended questions).

9. Burden Hour Computation

Survey Type	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response in hours or minutes	Total Hours
Pre-test survey screener	2,400	1	1	1 minute	48
Pre-test survey	1,200	1	1	15 minutes	300
Total					348

10. Dates(s) to be Conducted

The survey will be conducted immediately upon OMB approval to inform both FDA and CDC's communications with the public. The data collection must be conducted as soon as possible to assist FDA and CDC to protect the public's health and safety.

11. Requested Approval Date

March 31, 2023

12. FDA Contacts

Program Office Contact	FDA PRA Contact
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