U.S. FOOD & DRUG ADMINISTRATION

Testing Communications by FDA's Center for Devices and Radiological Health

OMB Control No. 0910-0678 – EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: Consistent with OMB approval, individual collection requests under the established Generic Clearance will continue to undergo review by FDA's Office of the Chief Scientists Human Subjects Protection Executive Officer (FDA IRB) and/or an accredited external IRB, senior leadership in the Center for Devices and Radiological Health (CDRH), and FDA Paperwork Reduction Act (PRA) specialists prior to submission. Also, in accordance with OMB approval, in **Question 2** we include a report summarizing the number of hours used, as well as the nature and results of the activities completed under the individual requests since last OMB review. In addition, consistent with OMB communication on flexibilities under the PRA and the use of Generic Clearances, individual submission requests will be those we believe are low in burden, similar in nature, and do not raise any substantive or policy issues. [1]

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is seeking to extend approval from the Office of Management and Budget (OMB) for the generic clearance, "Testing Communications by FDA's Center for Devices and Radiological Health." This generic ICR facilitates CDRH's efforts to assess the need for communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations.

FDA is authorized by section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated products.

FDA creates and uses a variety of media, including print (e.g., brochures, posters, fact sheets, information kits), broadcast (e.g., Public Service Announcements, videos, news releases), and electronic formats (e.g., Internet, listservs, CD-ROMs) to communicate with the public and health professionals about the risks and benefits of regulated products. To ensure that such health communication messages have the highest potential to be received, understood, and accepted by those for whom they are intended, FDA will conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). This type of research involves: (1) assessing audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, communication strategies, and public information programs; (2) testing these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions; and (3) evaluating the final communication products to determine the effectiveness of the messages and distribution methods.

[1] Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies (July 22, 2016).

Testing messages is a staple of best practices in communications research. Obtaining feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program.[2] The purpose of early testing is to improve materials and strategies while revisions are still affordable and possible. Testing can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which communication messages need to be modified should be greatly reduced.

Testing also aligns with FDA's mission to protect the public health. By identifying gaps in key areas of public health knowledge, evaluating the effectiveness of communication messages, and integrating knowledge gained through research/evaluation into practice, FDA will help ensure that the public has the information they need about FDA-regulated products. Testing communications is also in keeping with the "2024 Blueprint for the Use of Social and Behavioral Science to Advance Evidence-Based Policymaking"[3] recommendations to use exploratory interviews and usability testing to improve how digital content and information is presented to consumers, and it meets repeated calls from FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. Purpose and Use of the Information Collection

FDA intends to use this generic information collection to gather information through a variety of research methods for developing and testing communications by CDRH, such as those related to medical devices and radiation-emitting products. FDA plans to use the data collected under this generic clearance to:

- assess the need for communications on specific topics,
- assist in the development and modification of communication messages, and
- help tailor print, broadcast, and electronic media communications in order for them to have powerful and desired impacts on target audiences.

The information collected will serve three major purposes. First, formative research will provide qualitative information about target audiences – their needs, decision-making processes, and misperceptions – that is critical to initial communications planning and development. Different formative research will have different foci, depending on the audience addressed and the questions needing to be answered to develop effective communications. For example, FDA must explore consumers', patients', and caregivers' beliefs and perceptions to formulate the basic objectives of its risk communication campaigns. To effectively inform consumers, patients, and caregivers

[2]National Cancer Institute (NCI). *Making Health Communications Work: A planner's guide*, Pink Book. Pub. No. T068. Washington, DC: U.S. Department of Health and Human Services (HHS), August 2004.

[3] White House. Blueprint for the Use of Social and Behavioral Science to Advance Evidence-Based Policymaking, available at https://www.whitehouse.gov/wp-content/uploads/2024/05/Blueprint-for-the-Use-of-Social-and-Behavioral-Science-to-Advance-Evidence-Based-Policymaking.pdf, May 2024.

about the risks and benefits of product use, FDA must understand critical influences on people's decision-making process when choosing to use, not use, or stop using products regulated by FDA/CDRH. Qualitative information on decision-making processes will also give FDA a better understanding of the needs of its different target audiences.

FDA must also understand the general beliefs of healthcare professionals such as physicians, physician assistants, nurse practitioners, and nurses practicing in primary care and medical specialties; hospital staff such as social workers, IT or healthcare administrators; dentists or oral health professionals; physical, psychological, and occupational therapists; medical equipment and laboratory technicians; phlebotomists; and home health aides. Healthcare professionals play a key role in the use of medical devices and other products regulated by FDA/CDRH. FDA must determine their informational needs and the most effective communication channels and formats for reaching and educating them about new warnings and guidelines. This information will allow FDA to engage healthcare professionals as partners in safe and effective use of such products.

Second, initial testing will give FDA some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. Respondents may be asked to give their reaction to the messages in individual or group settings. Initial testing may provide information on any of the following factors:

- *Attention* - The extent to which factors such as language, placement, typography, and graphic images attract and hold the audience's attention.
- *Comprehension* – The extent to which communication messages clearly convey risks, both in terms of the needs of low-literacy audiences and with respect to plain language principles and design.
- *Personal Relevance and Self-efficacy* – Perceptions that communication messages apply to target audience members personally, that the information is considered important, and that target audience members feel they are capable of acting on the message.
- *Credibility* – Perceptions that communication messages are credible and are being issued by a trustworthy and knowledgeable source.
- *Acceptability* – Detection of negative reactions and the extent to which target audience members find communication messages to be offensive, unacceptable, or culturally insensitive.
- *Behavioral Intent* – The extent to which respondents think they will take action (for example, maintain radioactive technology according to specifications) as a result of seeing the communication messages.

Respondents' input and reactions to each of these areas provide insight into how target audiences may react and how the messages should be formulated or revised to communicate most effectively. Other information gathered on respondents' gender, age, socioeconomic level, race, ethnicity, and personal/family use of products provides a basis for evaluating whether the messages may be perceived differently by various segments of the audience. For example, selected age groups may find a particular message or graphic image more compelling than other age groups.

Third, as evaluative research, the collected information will allow FDA to ascertain the effectiveness of the messages and the distribution method in achieving the objectives of the message campaign. Evaluation of message campaigns is a vital link in continuous improvement of communications at FDA.

Systematic communications testing has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials. Through communications testing FDA is able to:

- Better understand characteristics of the target audience–its attitudes, beliefs, and behaviors–and use these in the development of effective risk communications;
- Design messages and select formats that have increased potential to influence the target audience's attitudes and behavior in a favorable way;
- Help determine promotion and distribution channels to reach the target audience with appropriate messages; and
- Expend limited program resource dollars wisely and effectively.

The targeted population responding to the particular questions, and the specific questions, will change depending on the particular topic in question.

OMB will, in general, provide feedback or approve the individual collections within ten working days. For FDA Rapid Message Testing, where the intent is to quickly test communications during the communication development process with small samples of target audience members (15 to 30 participants), the FDA will flag submissions as "5-Day Turnaround Requested for Rapid Message Test." FDA recognizes, however, that timing on any action may fluctuate based on a number of factors including the content of the particular individual collection request and competing priorities.

3. Use of Improved Information Technology and Burden Reduction

The information will be collected through one-on-one telephone or in-person interviews, focus groups, or self-administered surveys, depending upon the target audience being questioned, expectations about whether the information will be evaluated in an individual or group context, and the need to present visual stimuli (e.g., graphic displays of negative health outcomes). As computer technology has continued to improve and become more widespread, opportunities to test messages on the Internet using either Web-based surveys or online interviews and focus groups have increased. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the burden on respondents. For example, respondents can access and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for in-person or group interviews. Wherever possible, FDA will make use of Web-based data collection methods.

Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing maximally efficient. Possible information technologies for testing include Computer-Assisted Telephone Interviewing (CATI), Computer-Assisted Personal Interviewing (CAPI), Audio and Computer-Assisted Self-Interviewing (ACASI), Web-based surveys, online videoconferencing, internet conferencing, or teleconferencing.

4. Efforts to Identify Duplication and Use of Similar Information

Research conducted is not anticipated to duplicate any other evaluation or testing being completed by FDA or other federal agencies.

As each new communication message or strategy is developed, FDA reviews existing literature and databases, including testing reports on existing messages and materials. FDA also consults with outside experts to evaluate available information on similar messages with comparable audiences. In addition, FDA will be working with DHHS, AHRQ, CMS, as well as other government agencies that are responsible for communicating about use of medical products and elements that impact their performance, safety, and effectiveness within population segments or the general public.

However, because risk communications on the use of medical devices and radiological products will be diverse and vary by target audience, new data collection instruments generally will be prepared for each project. The areas in which testing of effective communication messages will be needed (as described in Q.2. above - attention, comprehension, etc.) are generally similar from project to project. However, the specific questions that are asked of respondents will differ with the message content, target audiences, and medium of the message.

5. Impact on Small Businesses or Other Small Entities

These proposed data collection activities will focus primarily on participants in their roles as individuals or healthcare professionals during their own time. In some instances, we might want to question hospital or other healthcare facilities staff. In most cases, we believe that such facilities are very unlikely to include small businesses, and we will strive to avoid including small businesses unless they are a targeted audience. If we believe that employees of small businesses should be examined, we will ensure understanding that the information collection is completely voluntary.

6. Consequences of Collecting the Information Less Frequently

FDA plans to use a variety of media, messages, and materials to inform and educate the public. Sound research and evaluation are needed as integral parts of communication design rather than as afterthoughts. It is important that the public understands communications about regulated products sufficiently well to make appropriate choices.

Without testing, FDA could be expending considerable funds on communications that would not achieve the intended purpose of improving public health. FDA intends to test as frequently as is appropriate to ensure that communications, especially highly impactful ones, are appropriately designed. Testing on an ad hoc basis will be needed to assess initial and continuing relevance of messages given dynamic social and environmental factors and the changing education and information needs of the public.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Because FDA's communications testing activities will be primarily qualitative in nature, the results are not generalizable to the population at large or the particular target audience under study.

However, the nature of communications testing is such that generalizability is not a critical feature; the emphasis is on obtaining timely, useful information that can be fed back into the development of new messages or materials or the revision of existing ones. There are no other special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of August 7, 2025 (90 FR 38155), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

As standard practice in commercial market research, and as has been approved by OMB in the past, interview and focus group participants may be offered an incentive for participation at a regionally appropriate market rate. Table 1 summarizes the upper limit of incentive rates that OMB will approve based on market rates alone and without FDA providing additional rationale.

Table 1.—Incentive Rates Not Requiring Additional Rationale

	Consumer, Patient, or Caregiver	Healthcare Professional—Primary Care	Healthcare Professional—Specialist
30-minute interview	$40	N/A	N/A
45-minute interview	$60	$125	$175
90-minute focus group	$100	$275	$325

FDA will provide additional rationale in the justification memo for any studies that propose to offer monetary incentives beyond the ranges specified in Table 1. For example, incentives for difficult-to-recruit medical specialists, may be offered at a higher rate, when additional justification is provided.

Circumstances, however, do not always require such incentives; many audiences including the public, patients, survivors, and some health professionals may participate because of their interest or involvement in the topic, or as a professional courtesy.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate 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 on behalf of the FDA by a contractor or vendor who conducts surveys. PII is collected to assess the need for communications on specific topics. 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 has 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 Privacy Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

The Freedom of Information Act (FOIA)

Under the FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b) (1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking a question about race, ethnicity, income, education and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as private.

Because FDA communications may be concerned with the prevention of premature mortality, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. The probability of sensitive questions occurring depends upon the topic of the communication. This information is needed to gain a better understanding of the target

audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, still require some sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1 is based on the maximum number of data collections expected on an annual basis. It is highly unlikely that respondents will be contacted more than once per year due to the variable nature of the medical product issues and the need to address different respondent groups.

Proposed data collection methodologies are described in more detail in Part B of this Supporting Statement.

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Individual In-Depth Interviews	420	1	420	0.75 (45 min.)	315
General Public Focus Group Interviews	288	1	288	1.50	432
Intercept Interviews: Central Location	200	1	200	0.25 (15 min.)	50
Intercept Interviews: Telephone	4,000	1	4,000	0.08 (5 min.)	320
Self-Administered Surveys	2,400	1	2,400	0.25 (15 min.)	600
Gatekeeper Reviews	400	1	400	0.50 (30 min.)	200
Omnibus Surveys	1,200	1	1,200	0.17 (10 min.)	204
TOTAL (General Public)	8,908				2,121
Healthcare Professional Individual In-Depth Interviews	72	1	72	0.75 (45 min.)	54
Healthcare Professional Focus Group Interviews	144	1	144	1.50	216
TOTAL (Healthcare Professionals)	216				270
TOTAL (Overall)	9,124				2,391

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents and length of response was determined based on FDA experience with communications testing and an estimate of the communication needs of the Center for Devices and Radiological Health.

12b. Annualized Cost Burden Estimate

Table 3. – Annualized Burden Costs[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs (rounded)
All Occupations (General Public)	2,121	$33.54	$71,138
Physicians – All Other (Healthcare Professionals)	270	$113.46	$30,634
Total			$101,781

[1] Figures rounded to the nearest whole dollar.

We assume the general public will complete the majority of data collections. The mean hourly wage rate for this group ("All Occupations") is $33.54.[4] The estimated annual cost for the general public (approximately 2,121 burden hours) is therefore $71,138 (rounded). Other labor groups include primary care physicians and medical specialists ("Physicians – All Other"), whose mean hourly wage rate is $113.46.[5] The estimated annual cost for healthcare professionals (approximately 270 burden hours) is therefore $30,634 (rounded). The total estimated annual cost is $99,045.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, or operating and maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Costs may include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting on findings. Because this request for generic clearance includes various procedures for the collection of information, contractor expenses may vary from an estimated $20,000 for a small message test to an estimated $250,000 for a larger focus group and in-depth interview study.

In addition, we estimate monitoring by the government Project Officer to be about 25% of a full time equivalent (FTE) employee's time per year. Assuming a cost of $367,125 per position (which is the agency's projected average cost of an FTE including benefits),[6] we estimate an annual staffing cost to the Federal government of $91,781.25 ($367,125 x 0.25 FTEs, rounded).

[4]Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (occupation code 00-0000) May 2023. https://www.bls.gov/oes/current/oes_nat.htm.
[5]Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (occupation code 29-1229) May 2023. https://www.bls.gov/oes/current/oes_nat.htm.
[6] Based on the FDA fully loaded FTE cost model (domestic) for FY 2026 as provided by agency economists.

The total estimated annual cost to the government for this collection of information is therefore $1,736,781.25. This is equal to the total of contractor expenses ($1,645,000) plus FDA government staff salary cost ($91,781.25).

15. Explanation for Program Changes or Adjustments

Based on our experience with the program since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The process for developing the analytical plan for communications testing is similar to that used in any formal evaluation. The staff will review the material to be tested, discuss the objectives with the individuals responsible for developing the materials, determine the analytic questions to be addressed, and then prepare the procedures, instruments, and data analysis plan. The analyses conducted for each project will be determined by the communication objectives, the messages being tested, and the audience for the messages. Specifics of the analyses cannot be determined until the messages to be tested are prepared.

Techniques include primarily qualitative analyses (for example, content analysis for in-depth interviews), although some results, including those from central location intercept interviews or Web-based surveys, are summarized quantitatively using descriptive statistics. In cases where quantitative data is collected, descriptive statistics—including percentages, cross tabulations, and measures of central tendency—will be calculated and presented, along with demographic descriptions of study respondents. Information collected from study participants will be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race, ethnicity, etc.). Statistical analyses may be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t-tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; non-parametric procedures will be used otherwise. All of the analyses will be done in the context of understanding the limitations of the data with respect to their not representing population parameters.

While the primary purpose of this data collection is to provide information to the developers of the messages for the purpose of improving them, FDA makes results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, FDA may present the findings of its work at professional association meetings, for example, the American Public Health Association. Some results may be published in professional journals such as the Journal of Public Policy and Marketing. In any findings presented at professional association meetings or in professional journals, FDA will state the limitations of the data by recognizing the qualitative and nonrepresentative nature of the results.

The specific messages to be tested and the timing of these messages are not known at this time. While the period varies somewhat depending on the complexity of the testing and number of respondents required, the typical communications testing project will require approximately 12 weeks once OMB clearance is obtained. A schedule for a typical project is shown below:

Typical Project Time Schedule

Activity	Time Schedule
Finalize materials	1 week after OMB approval
Finalize design	3 weeks after OMB approval
Collection of data	5 weeks after OMB approval
Analysis of data	10 weeks after OMB approval
Report on results	12 weeks after OMB approval

The schedule for rapid message testing with small samples of target audience members is condensed to about half this time (or six weeks).

Rapid Message Testing Project Time Schedule

Activity	Time Schedule
Finalize materials and design	1 week after OMB approval
Collection of data	3 weeks after OMB approval
Analysis of data	5 weeks after OMB approval
Report on results	6 weeks after OMB approval

We recognize that individual collections under this generic clearance may have slightly different timeframes from those outlined above.

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date and inform respondents of its significance in accordance with PRA requirements at 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.