UNITED STATES FOOD & DRUG ADMINISTRATION

Data Collections to Support Drug Product Communications

OMB Control No. 0910-0695 – Generic Clearance - EXTENSION

Terms of Clearance: *Consistent with OMB approval, individual collection requests under the established Generic Clearance will continue to undergo review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Center for Drug Evaluation and Research (CDER), 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[1] 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.*

SUPPORTING STATEMENT – Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency outreach and other proactive communication efforts. Evaluating communication messages and supporting materials in advance of a communication campaign provides an important role in improving FDA communications as they allow for an in-depth understanding of individuals' knowledge, attitudes, beliefs, motivations, feelings, and behaviors. Mandated by Congress to ensure the safety and effectiveness of medical products, including biologics, drugs, foods, cosmetics, medical products, radiological products, and animal drugs, we have established this generic information collection as a tool to help assess the need for FDA communications on specific topics pertaining to drug products we regulate. FDA is authorized to undertake formative and evaluative research under section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(D)), as well as section 301 of the Public Health Service Act (42 U.S.C. 241(a)). To maximize the effectiveness of drug product communications so that they have the highest potential to be received, understood, and utilized by those for whom they are intended, we plan to conduct individual information collections to support research and studies consistent with this authority.

Background:

As communicated on our website at https://www.fda.gov/about-fda/reports/strategic-plan-risk-communication#glance, we continue to identify actions the agency plans to take to improve risk communication to public audiences. These initiatives fall into the following three areas:

- **Strengthen the *science* that supports effective risk communication.**
- **Expand FDA *capacity* to generate, disseminate, and oversee effective risk communication.**

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

- **Optimize FDA *policies* on communicating risks and benefits.**

Rick Communications:

Risk and health communication research consistently shows the importance and benefits of conducting formative and evaluative studies to inform communications (Communicating Risks and Benefits: An Evidence-Based User's Guide https://www.fda.gov/about-fda/reports/communicating-risks-and-benefits-evidence-based-users-guide.) Through communications testing FDA is able to better understand characteristics of the target audience--their attitudes, beliefs, and behaviors--and use these to ensure effective risk communications that meet audiences' needs and desires and enhance their decision making; design messages and select formats that have increased potential to influence target audiences' attitudes and behavior in desirable ways; determine the best distribution channels; and expend limited program resource dollars wisely and effectively. To effectively inform consumers about the risks and benefits of use of drugs, FDA must understand critical influences on people's decision making when choosing to use, not use, or stop using drugs. FDA must continue to explore consumers' beliefs and perceptions about using medications to formulate the basic objectives of its risk communication efforts.

Target Audiences:

Qualitative and quantitative information on decision making processes will also give FDA a better understanding of the needs of its different target audiences. The data will not be directly used for the purposes of making regulatory or other policy decisions. To help achieve our strategic goals however, FDA must also understand the general beliefs, experiences, and behaviors of specific or target audiences. For example, healthcare professionals. Prescribers, including physicians, physician assistants, and nurse practitioners, nurses, and pharmacists also play a key role in the use of drugs. Among prescribers, FDA must determine the most appropriate target audiences for the informational needs and the most effective communication channels and formats for reaching and educating those audiences about new warnings and guidelines. This information will allow FDA to engage healthcare professionals as partners in the safe and effective prescribing and use of drugs.

Respondents' input and reactions 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 drugs 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.

In addition, initial studies 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, especially important when information must be posted or released prior to formative research as is often the case with information about new and emerging drug safety issues and public health emergencies (i.e., COVID-19).

Current Efforts:

Obtaining feedback from intended audiences during the development of messages and materials is crucial for the success of communication programs.[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 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 along with associated costs. Conducting formative and evaluative research is also consistent with Department of Health and Human Services (DHHS) objectives to increase the proportion of health communication activities that include research and evaluation.[3] 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 can better ensure that the public has reliable information needed about FDA-regulated products.

Scope of Activity:

We continue to create and utilize a variety of print (e.g., brochures, posters, fact sheets, information kits), broadcast (e.g., Public Service Announcements, video news releases, podcasts), and electronic media formats (e.g., Internet, listservs, CD-ROMs) to communicate with the public and health professionals about the risks and benefits of regulated products.

Planned research activities include:

(1) assessing audience knowledge, attitudes, beliefs, motivations, feelings, 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.

Data Collection Criteria::

Respondents may be asked to give reaction to simulated messages in individual or group settings. Initial studies may provide information on a variety of factors, including:

Attention - The extent to which factors such as language, placement, format, order, typography, and graphic images attract and hold the audience's attention.

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[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] U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000.

Comprehension – The extent to which communication messages clearly convey information and risks, including to address 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 able to act on the message.

Credibility – Perceptions that communication messages are credible and are being issued by a trustworthy and knowledgeable source.

Behavioral Intent – The extent to which respondents think they will take action as a result of seeing the communication messages, e.g., sharing a message with friends or on social media, talking with a health care professional about a new medication or a safety issue with a drug they have been prescribed.

Potential Unintended Consequences – Detection of potential negative reactions and the extent to which target audience members find communication messages to be offensive, unacceptable, or culturally insensitive.

We therefore request approval for this generic clearance of information collections to support drug product communications, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We expect data collected through individual requests under this generic clearance to serve two major purposes. First, formative research will provide qualitative information about target audiences, understanding their needs, their decision-making processes, and knowledge, attitudes and perceptions--that is critical to initial communications planning and development. Different formative research will have different foci, depending on the audience addressed and the research questions needing to be answered to develop effective communications. We discuss methodologies that will be utilized in administering the individual collection requests more fully in Part B of our supporting statement. Since last OMB review and approval of the generic clearance, we have conducted the following individual information collections:

Title of Collection	Participants	Use of Information	Hours Used
CDER Rapid Message Testing with Consumers – Prescription Stimulant Diversion Messaging	30 respondents (U.S. adults 18 or older) • Half prescribed a stimulant for ADHD; • Half used a prescription stimulant without a prescription.	Used to inform updates to prescription stimulant communications designed to prevent misuse and abuse.	98

Title of Collection	Participants	Use of Information	Hours Used
Combating the Infodemics Through Evidence-Based Misinformation Management Strategies – Phase I	6,000 respondents (U.S. adults 18 or older)	Study currently in progress; results pending, which will be used to inform a Phase 2 experiment	2,760
Dosage Form Presentations in Direct-to-Consumer Prescription Drug Television Advertisements: Semi-Structured Consumer Interviews	30 consumer respondents	Study currently in progress; we will use the results of this IC to better understand how consumers interpret and react to common dosage form presentations in prescription drug television ads, and to inform an experimental phase of the research that will follow.	150
Drug Disposal Message Communications	20 consumer respondents. Participants were patients (n=10) or caregivers (n=10) who reported that they, or someone they cared for, received a doctor's prescription for opioids, filled it in the last six months, and had leftover medication.	Used to inform updates to a Drug Disposal question and answer (Q&A) webpage.	90
Exploring Healthcare Providers' Practices, Perspectives, and Experiences Prescribing and Co-Prescribing Benzodiazepines and Opioid Analgesics	1,985 respondents screened (estimated), with n=24 (3 focus groups) with specialty healthcare providers (physicians, nurse practitioners, and physician assistants) practicing in mental health, neurology, or emergency medicine and who prescribed benzodiazepines either alone or in conjunction with opioids in the past 90 days.	The data from these remaining set of focus group were combined with the data from the other 13 focus groups that were part of this phase of the study (see 2 rows down) and the combined focus group findings were used to inform the Phase 2 interviews (see next row)	366.5
Exploring Healthcare Providers' Practices, Perspectives, and Experiences Prescribing and Co-Prescribing Benzodiazepines and Opioid Analgesics: Individual In-Depth Interviews	450 respondents screened (estimated), with n=30 (individual interviews) with healthcare providers (physicians, nurse practitioners, and physician assistants) who have prescribed benzodiazepines either alone or in conjunction with opioids in the past 90 days.	Study currently in progress; results pending and to be shared with relevant CDER staff to help inform center discussions and communications.	105

Title of Collection	Participants	Use of Information	Hours Used
Exploring Healthcare Providers' Practices, Perspectives, and Experiences Prescribing and Co-Prescribing Benzodiazepines and Opioids (CDER)	911 respondents screened (4.7 % response rate), with n=117 (13 focus groups) with healthcare providers (physicians, PAs, NPs) who have prescribed benzodiazepines either alone or in conjunction with opioids in the past 90 days, mainly consisting of primary care HCPs.	The data from this set of focus group were combined with the data from the other 3 focus groups that were part of this phase of the study (see 2 rows above) and the combined focus group findings were used to inform the Phase 2 interviews (see row immediately above)	327
Focus Groups: Adherence Potential and Patient Preference in Prescription Drug Promotion (CDER)	35 respondents, including 18 primary care physicians and 17 general population consumers.	Data used to refine measurement instruments for follow-on survey.	157
Formative Research Study to Understand the Impact of Generic Substitutes for Various Patient and Caregiver Populations	182 respondents including autoinjector and dry powder inhaler patients and caregivers to patients who used these products.	Information was used to understand patient perceptions of substituting generic drugs and resulted in 2 manuscript publications	48
One-On-One Interviews: Examination of Implied Claims in Direct-To-Consumer Prescription Drug Promotion	70 respondents, including 35 general population consumers and 35 cancer survivors.	Data was used to inform development of stimuli and measurement instruments for follow-on survey.	150
One-on-One Interviews: Tradeoff Analysis of Risk, Benefit, and Adherence Claims in Direct to Consumer and HCP Promotion (CDER)	35 physicians who spent at least 50% of their time in direct patient care of patients with type 2 diabetes and/or psoriasis and 70 consumers who self-identified as having been diagnosed with type 2 diabetes or psoriasis.	Data was used to inform development of stimuli and measurement instruments for follow-on survey.	126
Prescription Drug Promotional Landscape Interviews	58 respondents including consumers and healthcare providers	Data collection has not yet begun.	0
Prescription Drug Use Related Software Study (CDER)	36 respondents including consumers who had been diagnosed with and were receiving treatment for diabetes; and primary care physicians who treated diabetes.	Data used to refine measurement instruments for follow-on survey.	54
Rapid Message Testing with Consumer Panel - Additional Testing of Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications (CDER)	18 respondents ages 18 – 28 who had used a prescription or over-the-counter (OTC) medicine in the past for non-medical or recreational purposes, consisting equally of those who had and hadn't done so.	Used to inform communications warning about the dangers of misuse and abuse of easily obtainable OTC medicines.	45
Rapid Message Testing with Consumer Panel - Drug Safety Communication Landing Page and Format (CDER)	20 respondents (U.S. adults) who had taken a prescription medicine in the past 30 days	Used to inform updates to FDA's Drug Safety Communications website	90

Title of Collection	Participants	Use of Information	Hours Used
Rapid Message Testing with Consumers - Interchangeable Biosimilars Information	15 respondents (U.S. adults) diagnosed with conditions in one of following categories: arthritis, gastrointestinal, and/or skin.	Used to inform updates to an educational factsheet developed by FDA about biosimilars and interchangeable biosimilars.	27
Rapid Message Testing with Consumers - Paxlovid Information	30 respondents (U.S. adults) consisting of HCP, specifically: primary care providers physician assistants, nurse practitioners and pharmacists.	Used to inform updates to two question and answer (Q&A) documents and one screening checklist about Paxlovid	29
Rapid Message Testing with Consumers - Terminology Routinely Used in CDER Communications	30 respondents (U.S. adults), half of whom had used a prescription medicine in the past 30 days and half who had not.	Used to test 20 commonly used technical regulatory terms and their plain language alternatives for understanding by general health consumers.	98
Rapid Message Testing with Consumers - Terminology Routinely Used in CDER Communications (COVID-19 Message Testing)	30 respondents (U.S. adults), including parents and caregivers of children aged 5-9 (n=12), parents and caregivers of children aged 12-15 (n=8) and adults (n=10)	Used to inform updates to three question and answer (Q&A) documents about COVID vaccines.	98
Rapid Message Testing with Consumers Cannabis Consumer Update	20 consumer respondents who have screened in as current (past 30 day) users of delta-8, delta-10, HHC, or another hemp-derived cannabidiol.	Study currently in progress. Results will be shared with CDER Division of Health Communication to update consumer update website on potential effects of cannabis products.	90
Rapid Message Testing with Consumers Drug Shortage Infographic	16 respondents (U.S. adults) with personal experiences related to drug shortages.	Used to inform updates to an FDA drug shortage infographic.	87
Rapid Message Testing with Consumers and Healthcare Professionals - Children's Cough and Cold Consumer Update (CDER)	24 respondents (U.S. adults), including parents and caregivers of children younger than 18	Used to assess a draft FDA Consumer Update article about children’s cough and cold products	97
Studies to Enhance FDA Communications Addressing Biosimilar Drug Products: Patient and Caregiver Interviews (CDER)	30 respondents including patients with inflammatory arthritis (n=3); cancer (n=2); inflammatory bowel disease (n=3); skin conditions (n=2); diabetes (n=2) and caregivers of children with diabetes (n=2).	Used to inform updates a one-page infographic, a 3-page fact sheet, and a single video about biosimilars.	65
TOTAL			5,157.50

3. Use of Improved Information Technology and Burden Reduction

The information will be collected through one-on-one telephone, online 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 have increased to conduct communication studies through web-based platforms. Using computer-assisted 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 from places and often times that are convenient to them, eliminating the need to travel for in-person interviews or focus groups.

Wherever possible, FDA will make use of web-based data collection methods. Possible information technologies for testing includes the following.

Computer-Assisted Telephone Interviewing (CATI) - Surveys conducted by telephone are well suited to the use of computer-assisted telephone interviewing technology. CATI's technological capabilities include automated dialing, scheduling unanswered calls or interrupted interviews for efficient callbacks, random selection of respondents, automated skip patterns, instantaneous out-of-range checks, insertion of information from one question to guide a subsequent question, and the automated generation of databases for subsequent analysis. When telephone interviews are used, CATI will be employed whenever possible.

Computer-Assisted Personal Interviewing (CAPI) - CAPI technology allows interviewers to ask questions of a respondent using a computer to enter data. Some primary advantages of CAPI include:

- The elimination of routing and looping problems within a paper-and-pencil questionnaire.
- Respondents and interviewers cannot accidentally skip questions.
- Interview questions are customized to account for personal information provided by the respondent (e.g., respondent's age, information from previous questions).
- CAPI software can automatically perform mathematical calculations and tabulations.
- CAPI software checks for inadmissible or inconsistent responses.
- CAPI allows interviewers to administer surveys to geographically isolated groups, respondents without telephones or Internet access, or other difficult-to-reach populations.
- CAPI eliminates errors that arise from separate data entry.

Audio and Computer-Assisted Self-Interviewing (ACASI) - ACASI software technology offers many advantages of CAPI technology but removes the need to have a person administer an interview; instead, survey questions are pre-recorded and played back through the sound system of a computer, which the respondent can listen to privately by using headphones. Respondents select an answer by pressing a key that corresponds to one choice shown on the screen, after which answers are fed directly into a computer database. ACASI surveys can also be administered over a telephone by entering the response on the telephone keypad. ACASI technology is particularly useful in administering surveys to low- literacy populations or when addressing sensitive topics that respondents may not feel comfortable discussing in the presence of someone else.

Web-based Surveys - Web-based surveys, including those that include experimental components, are an effective way to gather data from large numbers of respondents that can

provide more representative findings. With web-based surveys, after providing consent to participate, respondents are shown questions and related possible answers on a computer screen through an online platform, and their selected answers are then submitted automatically over the Internet. The platform collects and collates these answers, which are provided to FDA with no PII. Closed-ended questions (e.g., multiple-choice items, Likert scales, true/false) will be employed whenever possible.

Videoconferencing - Videoconferencing uses audio and video and satellite technology to allow a group of focus group participants and/or a moderator and an individual interviewee located in multiple geographic locations to interact with one another both visually and aurally. A facilitator and a technical team located in a hub site maintain the video and audio connections among participating sites. Videoconferencing platforms are able to provide audio and video recordings and transcripts of each discussion to FDA researchers to ensure accuracy of data analysis and reporting.

Web conferencing - Web conferencing is especially useful for discussions with specific individuals or international participants. This format functions as a sort of "chat room" in which a moderator intercepts and distributes e-mail transmissions from participants who have logged onto a specially designated website.

Teleconferencing - Teleconferencing uses telephone technology to facilitate an exchange among participants located in multiple geographic locations and are able to provide audio-only recordings of discussions. Participants dial into a specially designated phone number or "bridge line" that is moderated by a focus group facilitator.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

These proposed data collection activities will focus primarily on individuals in their roles as health consumers, patients, and health professionals, including staff in hospitals or other healthcare facilities. In most cases, such facilities are very unlikely to include small businesses, and we will strive to avoid including small businesses unless they are a targeted audience to decrease the burden such collections might place on them. If we believe that employees of small businesses should be included, we will ensure understanding that the information collection is completely voluntary. We anticipate the burden on small businesses or other small entities as no more than one hour per respondent.

6. Consequences of Collecting the Information Less Frequently

The timeliness of the information requires a high frequency of collection. There is a reasonable expectation of significant developments between collections as it pertains to the approval of new products, as well as continued monitoring of products already on the market. In some cases, reducing the frequency of collection could undermine efforts to timely deliver important drug product communications to vulnerable populations.

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

There are no special circumstances for this collection of information.

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

We published a 60-day notice for public comment in the Federal Register of September 29, 2023 (88 FR 67311). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

While it is common practice in social science research to offer recruited participants a token of appreciation for time spent engaged in personal interview activities, we will consider offering incentives on a case-by-case basis, depending upon the topic, target audience, length of participation, and the particular information collection design. In cases where money is offered as an incentive for participation in in-person interviews, we will provide a rationale in our justification memo for any studies that propose to offer rates beyond this range. Incentives for difficult-to-recruit populations may be offered at a higher rate. As discussed previously, FDA product communications are often intended to reach a target audience. Although we may offer what we believe is a nominal incentive to gather feedback, we also believe that, in some cases, those respondents targeted are uniquely able to provide the information we seek and best represent those to whom product communications are intended to reach.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii) and agency regulations in 21 CFR § 20.20, data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, 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, date of birth, age, race, gender, and ethnicity. A contractor, or sub-contractor will be collecting PII and does so as part of their normal course of business. The PII is not collected on behalf of the FDA since information collection is from an existing participant pool and many agencies or companies benefit from the information collected. Information collected by the contractor, or sub-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. The PII provided to FDA in aggregate form will allow FDA to better understand patients', consumers', and health care providers' perceptions, attitudes, behaviors, and patient reported outcomes associated with efficacy, safety, and use of drug products overseen by the agency. All information collected will be kept secure by the contractor. The contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors 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 study 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).

We have 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, FDA nor its contractors use *name* or any other personal identifier to retrieve records from the information collected.

The Freedom of Information (FOIA)

Under 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 participants who meet characteristics of a target population that FDA is trying to better understand or reach. This may require asking questions that are standard in research but may be considered sensitive by some, e.g., race/ethnicity, income, education and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Such questions may also be asked as part of survey studies to enable researchers to determine if there are differences across groups, (e.g., different age groups may have different channels through which prefer to obtain health information). All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (https://www.whitehouse.gov/wp-content/uploads/2017/11/Revisions-to-the-Standards-for-the-Classification-of-Federal-Data-on-Race-and-Ethnicity-October30-1997.pdf).

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 and method of the communication study. This information is needed to gain a better understanding of the target audience(s) so that messages, strategies, and materials will be appropriate. 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 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. As noted in section 10. above, participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The informed consent form and the interviewer/moderator for interviews/focus groups makes it clear that participants do not have to respond to any question(s) that makes them uncomfortable.

Raw data from data collections that may include sensitive information (for example, screening questionnaires and audio tapes) will not be retained once the data have been extracted and

aggregated. The information never becomes a part of a system of records containing permanent identifiers that can be used for retrieval.

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 our supporting statement, Part B.

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

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (In hours)	Total Hours
Individual In-Depth Interviews	820	1	820	0.75 (45 minutes)	615
General Public Focus Group Interviews	1500	1	1500	1.50 (90 minutes)	2,250
Intercept Interviews: Telephone	15,900	1	15,900	0.08 (5 minutes)	1,272
Self-Administered Surveys	22,300	1	22,300	0.33 (20 minutes)	7,359
Gatekeeper Reviews	1,000	1	1,000	0.50 (30 minutes)	500
Omnibus Surveys	3,100	1	3,100	~0.38 (23 minutes)	1,184
Total (General Public)			44,620		13,180
Healthcare Professional Focus Group Interviews	380	1	380	1.50 (90 minutes)	570
Total (Overall)			45,000		13,750

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

12b. Annualized Cost Burden Estimate

The general public will complete the majority of data collections. The average salary for this group, Business Operations Specialists, is $40.04.[4] The estimated annualized annual cost for the general public in this information collection for 12,523 hours of reporting time is $501,420.92. Other labor groups include primary care physicians and medical specialists, whose average salary, respectively, is estimated as $121.15[7] and $146.50[7]. The estimated annualized annual cost for healthcare professionals in this information collection for 570 hours of reporting time is $152,560.50 ($121.15 x 570 hours = $69,055.50 and $146.50 x 570 hours = $83,505). The estimated annualized annual cost for 13,093 hours of reporting time is $653,981.42. The number of respondents and length of response was determined on the basis of FDA prior experience with communications testing and an

[4] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, May 2022.

estimate of the communication needs of the Center for Devices and Radiological Health. The actual numbers will vary depending upon the topic of interest.

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

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

14. Annualized Cost to the Federal Government

Costs will 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 focus group study to an estimated $150,000 for an in-depth interview study. The maximum estimated annualized expense for contractor expenses in this data collection is $2,180,000.

In addition, government staff costs may be incurred for monitoring by the government Project Officer, projected to be about 25% of a full-time equivalents (FTE) per year (520 hours). Assuming a cost of $321,053 per one FTE (salary plus overhead, full-time 40-hour week) divided by the total number of hours worked (2,080 hours) per year, the fully loaded wage rate is $156 per hour. We calculate the annualized cost to the Federal Government is $81,120 ($156/hour x 520 hours).

The total estimated annual cost to the government for this collection of information is $2,261,120. This is equal to the total of contractor expenses ($2,180,000) plus FDA government staff salary cost ($81,120).

15. Explanation for Program Changes or Adjustments*

We have increased our burden estimate since last review of the information collection to allow for additional individual requests under the approved generic clearance. We also note an inadvertent publication error in our *Federal Register* notice of March 6, 2024 (89 FR 16002) reflecting a total of **3**3,750 burden hours, but have clarified in this supporting statement our request for **1**3,750 burden hours, and 45,000 responses. Lastly, while we have made no program changes, we have included additional details regarding the scope of collection in Q-1 of the supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The process for developing the analytical plan for communications studies are 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 study objectives, the topic of, the audience(s), research questions, and data collection method (e.g., interviews, surveys). Specifics of the analyses cannot be determined until the study materials are prepared.

Techniques include qualitative analyses (for example, thematic or content analysis), and quantitative analyses. In cases where quantitative data is collected, descriptive statistics

including percentages, cross tabulations, and averages--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 analyses will be done in the context of understanding the limitations of the data with respect to their not representing population parameters.

Under certain circumstances, materials approved under this generic clearance may be subject to changes that affect the look and feel of collection, but do not change the nature or type of information collected. Changes which do not increase the burden of a collection, though they might reduce its burden (e.g., a cosmetic change to the colors, visual layouts, or field sizes of a collection form) may be made, as long as the underlying, approved form is not altered, and the materials essentially collect the same information.

Although the primary purpose of this data collection is to provide information to aid communication professionals in development and improvement of agency messages and materials, the results of these studies are shared within FDA to enhance understanding about topics of interest and audiences. FDA also may make these results available to staff at other Government agencies, health professional and patient advocacy organizations, and medical institutions. In addition, FDA may present the findings of its studies at professional association meetings, including the American Public Health Association.

Some results may be published in professional journals such as the Journal of Public Policy and Marketing. When presenting or publishing findings, including at professional meetings or journals, FDA will state the study limitations, including the non-representative nature of the results, where appropriate.

The specific topics, messages, and/or materials to be studied, and the timing and length of these studies varies depending on a number of factors, including the complexity of the topic, data collection method, number and type of participants, research questions to be answered, and analyses to be conducted, and thus are not known at this time. While some communications studies take significantly longer, a simple message/material - testing project typically can be completed within approximately 12 weeks once OMB clearance is obtained. A schedule for a typical project is shown below:

Project Time Schedule:

Activity	**Output**
Recruit participants	3 weeks after OMB approval
Collection of data	5 weeks after OMB approval
Analysis of data	10 weeks after OMB approval
Report results	12 weeks after OMB approval

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

The OMB expiration date will be displayed on the collection instruments.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.