FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "Testing Communications on Drugs" (0910-0695)

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel — Drug Safety Communication (DSC) Landing Page and Format

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   Drug Safety Communications (DSCs) are FDA's primary tool for communicating important new and emerging drug safety information to the public. DSCs represent FDA's independent scientific analyses of a drug safety issue and our communication of that information to the public. Each DSC is distributed to more than a million listserv subscribers and social media followers, and is viewed many thousands of times on the FDA website alone.

   The purpose of this project is to conduct testing of proposed revisions to the DSC landing page on FDA's website. For testing purposes, we will show participants a PDF mock-up of the website because it is not possible for FDA to share publicly pre-production web content. The mock-up includes key hyperlinks that will enable participants to navigate the PDF similar to the way they would the actual website. We will elicit participants' feedback on proposed landing page text that aims to briefly explain in plain language what DSCs are, how FDA reviews and approves drugs using clinical trial data, how new safety issues may be uncovered after drug approval, and that patients and healthcare professionals can subscribe to email alerts about DSCs.

   Additionally, we will elicit feedback from participants on the content of the Q&A "ribbon" text of DSCs, using the March 2020 communication about montelukast (Singulair) as an example that participants might recognize as a commonly used medication to treat allergies and asthma. CDER/Office of Communications conducted a number of research studies over a multi-year period related to the content and format of the DSCs. The latest of these, which involved qualitative research in the form of focus groups followed by in-depth individual interviews and then by an experimental study, all with general health consumers, resulted in the determination that this current "ribbon" format performed more effectively than an alternative possibility; similarly for the ribbon text, the question format performed more effectively than the statement format. The content of the ribbon text was informed by the risk communication literature and validated approaches, and by the findings from the focus groups and interviews. We will obtain feedback from participants on whether the questions provided in the example DSC's Q&As are those they want answered and whether they have any suggested improvements for the usability of the "ribbon" format.

   Communications science tells us that we must test messages with our intended audiences. Thus, FDA plans to test these communications using cognitive interviews with a small sample of 20 U.S. adults drawn from a diverse consumer panel.

This data collection is the 22nd in a series of FDA rapid message tests with consumers submitted to OMB under generic clearance. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order[1] to improve how information is presented to consumers by applying behavioral science insights, 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. **Intended use of information:**

FDA's contractor Westat will test the PDF mock-up of the website with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for FDA, and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

FDA will use the collected interview data to refine its messaging by improving the comprehensibility and personal relevance for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

- How well does the landing page meet participants' expectations?
- Is the landing page text clear and understandable? How well does the text describe how new safety issues for medicines surface and what DSCs are?
- What is the main message that participants get from the landing page? How well does this align with FDA's goals of communicating that: (a) new safety issues may be uncovered with approved medicines; (b) DSCs provide important information about these safety issues; and (c) the public can subscribe to receive email alerts about DSCs?
- How well do participants think the landing page is organized?
- How would participants attempt to find a DSC for a specific medicine? How well does this align with their expectations for how to find a DSC for a specific medicine?
- How intuitive do participants find the "See more" button under Current Drug Safety Communications?
- Are the instructions for subscribing to DSCs clear and easy to find?
- What improvements do participants suggest for the landing page?
- Are the questions listed under the sample DSC the ones that participants want answered?
- How intuitive do participants find the drop-down format to see answers to each question? What would make it more intuitive?
- What improvements do participants suggest for the DSC formatting?

[1] https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american

The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

We will conduct 20 45-minute interviews with U.S. adults. Westat has partnered with Plaza Research, a recruitment specialist to recruit respondents from its general population panel. Plaza Research tracks and stores all database member activity and assigns a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile information provided during enrollment, profile updates, and past focus group or in-depth interview involvement. Plaza monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include individual vetting of contact information, and review of enrollment data, as well as review of screener questions, rescreening of participants before participation, and client feedback on past focus group and interview response.

We will use a participant screener to recruit consumers who have taken a prescription medicine in the past 30 days. We will primarily recruit lower education patients (high school or less) for feedback on literacy and comprehension. To the extent possible, the participant pool will be diverse in terms of gender, age, race/ethnicity, and geography.

4. **Date(s) to be Conducted:**

We plan to conduct interviews in April 2021.

5. **How the Information is being collected:**

We will conduct all interviews remotely using telephone and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, or tablets. We will ensure that any materials provided to the participants for the test are compatible with these devices. We will email materials to participants who do not have access to screen sharing technology.

For each 45-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

Note takers will chart their findings into a standardized reporting template so that all notes are organized in a consistent manner. Interviewers will review the notes to ensure accuracy. With the consent of participants, we will audio record each interview.

FDA staff will have the ability to listen to the interview sessions, and this will be made known to participants as part of the informed consent.

6. **Confidentiality of Respondents:**

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked whether they allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins. Participants who do not allow audio recording will not be invited to participate in the interview.

No participant's identifiable information such as name will be included in the interview notes. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Interview notes will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to FDA, Westat will destroy all names and contact information of participants to protect their personal identity. Additionally, the interview notes and interpretive report delivered to FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas. Data collected in hard copy will be kept in locked cabinets when not in use.

FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

7. **Amount and justification for any proposed incentive**

For this project, Plaza Research will provide $50 incentives to participants at the end of each 45-minute interview in the form of a check.

Plaza Research uses a "by-invitation-only" recruitment methodology and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. Plaza's incentive scale is based on set time increments and is applied equally across all study topics, sponsors, and data collection modes. The table below details the previous incentives approved by OMB for this series of rapid message tests.

Project #	Communication Tested	Interview Length/Incentive	OMB approval date
1	Clinical Trials Brochure	45 min/$50	August 4, 2017
2	Caregiver Tipsheet	30 min/$35	September 26, 2017
3	Public Service Announcement Video about Generic Drugs	30 min/$35	October 25, 2017
4	Opioid Analgesics Patient Counseling Guide	45 min/$50	November 27, 2017
5	Vaccines and Seniors Brochure	30 min/$35	May 10, 2018

6	Public Service Announcements about Safe Disposal of Opioids	30 min/$35	July 26, 2018
7	Nicotine Dialogue Campaign Branding	30 min/$35	August 23, 2018
8	Testosterone Medication Guide	45 min/$50	October 12, 2018
9	Asthma Fact Sheet	30 min/$35	February 12, 2019
10	Transmucosal Immediate Release Fentanyl Risk Evaluation Mitigation Strategy Program Patient-Prescriber Agreement Form	45 min/$50	April 4, 2019
11	BeSafeRx Campaign Messages	45 min/$50	May 17, 2019
12	Safe Drug Disposal Notecard	30 min/$35	June 28, 2019
13	Medical Countermeasures	45 min/$50	September 10, 2019
14	Warnings on Opioid Packaging	30 min/$35	October 22, 2019
15	Messages About Cannabidiol (CBD)	30 min/$35	January 2, 2020
16	FDA's Purple Book Website	45 min/$50	January 16, 2020
17	Storyboards about Safe Disposal of Opioids and Other Medicines	45 min/$50	April 14, 2020
18	Medication Guide Template for Buprenorphine Products	30 min/$35	May 13, 2020
19	Retest Warnings on Opioid Packaging	30 min/$35	June 19, 2020
20	Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	45 min/$50	December 9, 2020
21	Additional Testing of Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	45 min/$50	March 12, 2021

8. **Questions of a Sensitive Nature**

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals' reactions to the messages and materials.

Nevertheless, respondents will be told that they may skip any question that they do not want to answer or may stop participating at any time.

9. **Description of Statistical Methods**

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme-based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to

original data, in this case the interview notes. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us import interview notes, create links between the notes and the Framework matrices, and develop new queries or matrices as needed.

The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

Bibliography

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, 18(1), 59-82.

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In *Qualitative research practice.* London: Sage Publications.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	1500	3	75
Interviews	20	45	15
		Total	**90**

REQUESTED APPROVAL DATE: April 7, 2021

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