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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel —Messages About Cannabidiol (CBD)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products. FDA is committed to making sure the public and consumers are aware of what we know to date. As we learn more, our goal is to update the public with the information needed to make informed choices about CBD products.

   The purpose of this project is to conduct timely consumer testing of messages about the known risks and side effects of using CBD products, as well as unknown aspects about CBD. Communications science tells us that we must test messages with our intended audiences before communicating them. Thus, FDA plans to test this communication using cognitive interviews with a small sample of 16 U.S. adults drawn from a diverse consumer panel.

   This data collection is the 15th in a series of FDA rapid message testing projects 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 communication 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

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

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:

- Are the risks clear and understandable?
- What is the main message that participants get from the material?
- What do participants recognize as the call to action?
- Do participants indicate that any of the material's information is new to them?
- Do participants find any of the warnings concerning?
- What information do participants find useful? Not useful?
- Do participants understand the grouping of the information into 3 categories?
- Is there information that is missing or that would be helpful to add?

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 16 half hour interviews with U.S. adults. Westat has partnered with Prodege, LLC, a leading provider of people driven insights for the market research industry. Prodege tracks and stores all panel member activity and assigns a unique ID number which stays with the panelist throughout their entire panel membership. These tracking records consist of profile information provided during enrollment, profile updates, and client feedback. Prodege monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include an enrollment verification process that includes digital fingerprinting, physical address and device verification, CATPCHA (a program that protects computers against bots), and mobile verification. Screener and survey responses are also monitored with internal quality metrics to ensure data quality.

We will use a participant screener to recruit a mix of consumers who have used CBD in the past 30 days and who have never used CBD. To help ensure the communication is understandable to those with lower health literacy, we will mainly recruit those with a high school education or less, with a few participants having some college. 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 January 2020.

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, tablets or mobile phones. We will ensure that any materials provided to the participants for the test are compatible with all devices.

For each 30-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 may still participate in the interview. In these cases, Westat will take notes that are more detailed than when relying on the audio recording.

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, Prodege will provide $35 incentives to participants at the end of each 30-minute interview in the form of a gift card.

Prodege uses diverse recruitment methodologies, including invitation, and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. 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

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

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

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.

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	75	3	4
Interviews	15	30	8
		Total	**12**

REQUESTED APPROVAL DATE: January 3, 2020

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
Ila.Mizrachi@fda.hhs.gov
(301)796-7726

Brian Lappin
CDER/Office of Communications
Brian.Lappin@fda.hhs.gov
(301)796-9126

FDA CENTER: Center for Drug Evaluation and Research (FDA/CDER)