

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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel
—Medication Guide Template for Buprenorphine Products

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The purpose of this project is to conduct timely message testing of a revised Medication Guide template for buprenorphine transmucosal drug products for the treatment of opioid dependence (BTOD). Medication Guides are paper handouts that come with many prescription medicines and are also available online. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.

The Medication Guide is part of the BTOD Risk Evaluation and Mitigation Strategy (REMS) Program. The REMS Program helps ensure that the benefits of the drug outweigh its risks. Prior surveys conducted as part of the BTOD REMS assessment have shown that respondents have had suboptimal knowledge of interactions with central nervous system depressants and lack awareness of serious side effects such as opioid withdrawal and life-threatening breathing problems. The revised BTOD Medication Guide aims to more clearly and succinctly communicate to patients:

- Accidental use of the drug product by a child is a medical emergency and can result in death.
- The drug product may cause serious and life-threatening breathing problems.
- Severe drowsiness, decreased awareness, breathing problems, coma, overdose or death can happen if you take the drug product with other opioid medicines, benzodiazepines, sleeping pills, sedatives, tranquilizers, antihistamines, or antidepressants.

Communications science tells us that we must test with our intended audiences before communicating them. Thus, FDA plans to test these communications using cognitive interviews with a small sample of 16 U.S. adults.

This data collection is the 18th 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 Order¹ 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.

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

2. **Intended use of information:**

FDA's contractor Westat will test the Medication Guide 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:

- Is the Medication Guide clear and understandable?
- What is the main message that participants get from the Medication Guide?
- Do participants recognize the call to action of seeking emergency medical care right away if they experience any of the listed symptoms, or if a child accidentally takes the medicine?
- Do participants understand when naloxone should be used?
- What information do participants find useful? Not useful?
- What do participants understand from the information about how the medicine should, and should not, be taken?
- What do participants understand from the information about how the medicine should be stored?
- Is the general layout appealing?

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 30-minute interviews with U.S. adults. Westat has partnered with EurekaFacts, a market research firm specializing in recruiting hard-to-reach audiences. EurekaFacts uses a number of outreach methods, including internal respondent lists, targeted calling, and community outreach to recruit diverse populations. EurekaFacts tracks and stores all respondent activity on secure servers and assigns a unique ID number to all respondents to track participation. EurekaFacts is certified to the ISO 20252:2012 market, opinion, and social research quality standard.

We will use a participant screener to recruit a mix of eight sublingual buprenorphine patients (the target audience) and eight lower education consumers (for feedback on literacy and comprehension). EurekaFacts will use established connections at treatment facilities, community centers, community clinics, and non-profits to recruit sublingual buprenorphine patients who have taken the drug in the past 12 months for the treatment

of opioid use disorder. To ensure feedback from lower literacy participants, EurekaFacts will sample consumers with a high school education or less from its general consumer panel. 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 May 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 these devices. We will email materials to participants who do not have access to screen sharing technology.

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, EurekaFacts will provide \$35 incentives to participants at the end of each 30-minute interview in the form of a check.

EurekaFacts uses diverse recruitment methodologies, including invitations and lists, and incentivizes any respondents for any participation to maintain a quality recruitment. Respondents 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
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

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.

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	100	3	5
Interviews	16	30	8
		Total	13

REQUESTED APPROVAL DATE: May 18, 2020

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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.