

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

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel
—Testosterone Medication Guide

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 for Androgel 1%, a prescription medicine that contains testosterone. Medication Guides are paper handouts that come with many prescription medicines. 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 Androgel 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 Androgel REMS assessment have shown that respondents have had difficulty in identifying certain early signs and symptoms of puberty in children inadvertently exposed to testosterone through direct contact with men using Androgel. A goal of the revised Androgel Medication Guide is to more clearly communicate to patients the signs and symptoms that might be noticed in women and children exposed to the medication.

Communications science tells us that we must test messages with our intended audiences before communicating them. Thus, FDA plans to test this communication using online cognitive interviews with a small sample of 15 U.S. adult men drawn from a diverse consumer panel.

This data collection is the eighth 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.

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

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, enhancing the cultural appropriateness and sensitivity, and improving the personal relevance for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

- Is the guide clear and understandable?
- What is the main safety message that participants get from the guide?
- Is the guide effective in conveying the knowledge of the signs and symptoms in children and women when they come in direct contact with Androgel 1%?
- Does the guide provide useful information about how to use Androgel 1% to avoid accidental exposure to women and children?
- Do participants recognize the call to action of stopping use of Androgel 1% and calling their healthcare provider if they see signs or symptoms in a child or woman that may have been exposed to the medication?
- 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 15 45-minute interviews with U.S. adult men. Westat has partnered with Research Now Group, Inc., a global leader in digital data collection, to recruit respondents from its general population research panel and avoid “professional” panelists through proprietary recruitment and enrollment techniques. Research Now 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, survey screeners, past survey participation, and client feedback. Research Now monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include participation limits, screening questions, digital fingerprinting, random and illogical responding, capturing and removing flatliners and speeders, and more.

We will use a participant screener to recruit a mix of men between the ages of 40 to 59 who are either living with children or not living with children. The participant pool will be diverse in terms of race/ethnicity, education, and geography.

4. Date(s) to be Conducted:

We plan to conduct interviews in October 2018.

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 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 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 IRB, the Research Involving Human Subjects Committee (RIHSC) 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, Research Now will provide \$50 incentives to participants at the end of each 45-minute interview in the form of virtual currency. The virtual currency is redeemable for a wide range of award items, vouchers, and publications.

Research Now 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. Research Now’s incentive scale is based on set time increments and panelist profiles 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. Questions of a Sensitive Nature

We do not anticipate asking any sensitive questions in the interviews. Instead, the questions will focus on individuals’ experience with prescription medications and their reactions to the messages and material.

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	250	3	13
Interviews	15	45	11
		Total	24

REQUESTED APPROVAL DATE: October, 2018

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References:

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.